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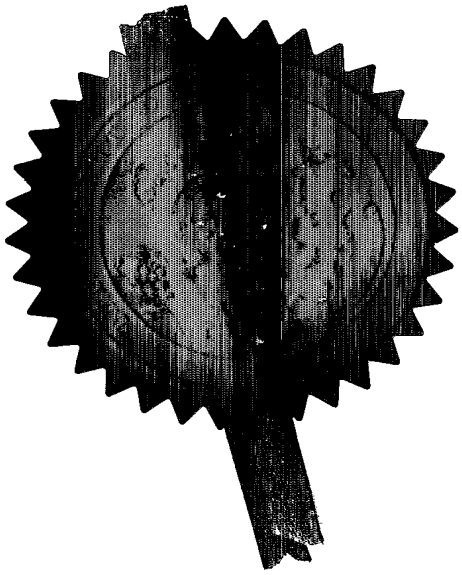

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Dated 1 June 2005

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1. Your reference

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28 APR 2004

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0409443.9

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

Smith & Nephew plc
15 Adam Street
London WC2N 6LA
United Kingdom

Patents ADP number *(if you know it)*

03969284001

If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention

Apparatus

5. Name of your agent *(if you have one)*

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

Peter Draggett
Group Patents & Trade Marks
Smith & Nephew plc
Research Centre
York Science Park
Heslington
York YO10 5DF
United Kingdom

Patents ADP number *(if you know it)*

03969284004

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Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

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Answer YES if:

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Continuation sheets of this form	
Description	62 ✓
Claim(s)	
Abstract	1 ✓ W-
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Priority documents	
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Statement of inventorship and right to grant of a patent (Patents Form 7/77)	
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11. I/We request the grant of a patent on the basis of this application.

Signature(s) P. J Draggett Peter Draggett Date 27 April 2004

12. Name, daytime telephone number and e-mail address, if any, of person to contact in the United Kingdom Peter Draggett 01904 824051

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APPARATUS

The present invention relates to apparatus and a medical wound dressing for aspirating, irrigating and/or cleansing wounds, and a method of treating wounds using such apparatus for aspirating, irrigating and/or cleansing wounds.

It relates in particular to such an apparatus, wound dressing and method that can be easily applied to a wide variety of, but in particular chronic, wounds, to cleanse them of materials that are deleterious to wound healing, whilst distributing materials that are beneficial in some therapeutic aspect, in particular to wound healing.

Aspirating and/or irrigating apparatus are known, and tend to be used to remove wound exudate during wound therapy. In known forms of such wound therapy, aspiration and irrigation of the wound take place sequentially.

Each part of the therapy cycle is beneficial in promoting wound healing:

Aspiration applies a negative pressure to the wound, which is beneficial in itself in promoting wound healing by removing materials deleterious to wound healing with the wound exudate, reducing bacterial load, combating peri-wound oedema and encouraging the formation of wound bed granulation tissue.

Irrigation cleanses wounds of materials that are deleterious to wound healing by diluting and moving wound exudate (which is typically relatively little fluid and may be of relatively high viscosity and particulate-filled.

Additionally, relatively little of beneficial materials involved in promoting wound healing (such as cytokines, enzymes, growth factors, cell matrix components, biological signalling molecules and other physiologically active components of the exudate) are present in a wound, and are not well distributed in the wound, i.e. they are not necessarily present in parts of the wound bed where they can be potentially of most benefit. These may be distributed by irrigation of the wound and thus aid in promoting wound healing.

The irrigant may additionally contain active amounts of materials that are beneficial in promoting wound healing which pass into and/or through the wound in contact with the wound bed.

If aspiration and irrigation therapy is applied sequentially to a wound, the two therapies, each of which is beneficial in promoting wound healing, can only be applied intermittently.

Thus, the wound will lose the abovementioned known beneficial effects of aspiration therapy on wound healing, at least in part, while that aspiration is suspended during irrigation.

Additionally, for a given aspirant flow, whilst materials that are potentially or actually deleterious in respect of wound healing are removed from wound exudate, the removal in a given time period of application of the total irrigate and/or aspirate therapy will normally be less effective and/or slower than with continuous application of aspiration.

Even less to be desired, is that while aspiration is not applied to the wound, wound exudate and materials deleterious to wound healing (such as bacteria and debris, and iron II and iron III and for chronic wounds proteases, such as serine proteases) will pool on the wound bed and hinder wound healing, especially in a highly exuding wound. This is especially the case in chronic wounds.

Depending on the relative volumes of irrigant and wound exudate, the mixed exudate-irrigant fluid and may be of relatively high viscosity and/or particulate-filled. Once it is present and has pooled, it may be more difficult to shift by the application of aspiration in a conventional sequential aspirate – irrigate – dwell cycle than with continuous simultaneous aspiration of the wound, owing to the viscosity and blockage in the system.

The wound will also lose the abovementioned beneficial effects of irrigation therapy on wound healing, at least in part, while that irrigation is suspended during aspiration.

These benefits in promoting wound healing include the movement of materials that are beneficial in promoting wound healing, such as those mentioned above and the supply in the irrigant of active amounts of materials that are beneficial in promoting wound healing which pass into and/or through the wound in contact with the wound bed.

Additionally, for a given irrigant flow, cleansing of the wound and the distribution by irrigation of the wound of such beneficial materials and the supply in the irrigant of active amounts of materials that are beneficial in promoting wound healing in a given time period of application of the total irrigate and/or aspirate therapy when such therapy is in a conventional sequential aspirate – irrigate – dwell cycle will normally be less effective and/or slower than with continuous application of aspiration.

Such known forms of aspiration and/or irrigation therapy systems also often create a wound environment that may result in the loss of optimum performance of the body's own tissue healing processes, and slow healing and/or in weak new tissue growth that does not have a strong three-dimensional structure adhering well to and growing from the wound bed. This is a significant disadvantage, in particular in chronic wounds.

The relevant devices tend not to be portable.

It thus would be desirable to provide a system of aspiration and irrigation therapy for a wound, which
can remove wound exudate and materials deleterious to wound healing from contact with the wound bed,
whilst simultaneously cleansing it and distributing materials that are beneficial in promoting wound healing across it; and
supplying in the irrigant active amounts of materials that are beneficial in promoting wound healing which pass into and/or through the wound in contact with the wound bed.

It is an object of the present invention

a) to obviate at least some of the disadvantages of known aspiration and/or irrigation therapy systems, and

b) to provide a system of therapy which can remove materials deleterious to wound healing from wound exudate, whilst retaining materials that are beneficial in promoting wound healing in contact with the wound bed, and

c) further supplies fluids containing active amounts of materials that are beneficial in promoting wound healing to pass into and/or through the wound in contact with the wound bed.

It is a yet further object of the present invention

a) to obviate at least some of the abovementioned disadvantages of known systems, and

b) provide a system that is portable.

Vascular supply to, and aspiration in, tissue underlying and surrounding the wound is often compromised.

It is a further object of the present invention to provide a system of therapy that also promotes vascular supply to tissue underlying and surrounding a wound, promoting wound healing.

Thus, according to a first aspect of the present invention there is provided an apparatus for aspirating, irrigating and/or cleansing wounds, comprising

a) a fluid flow path, comprising a conformable wound dressing, having
a backing layer which is capable of forming a relatively fluid-tight seal or closure over a wound and
at least one inlet pipe for connection to a fluid supply tube, which passes through and/or under the wound-facing face, and
and at least one outlet pipe for connection to a fluid offtake tube, which passes through and/or under the wound-facing face,
the point at which the or each inlet pipe and the or each outlet pipe passes through and/or under the wound-facing face forming a relatively fluid-tight seal or closure over the wound;

b) a fluid reservoir connected by a fluid supply tube to an inlet pipe via optional means for supply flow regulation;

c) optionally means for aspirate flow regulation, connected to a fluid offtake tube:

d) means for supplying physiologically active agents to the wound; and

e) at least one device for moving fluid through the wound dressing;

characterised in that it comprises

f) means for providing simultaneous aspiration and irrigation of the wound, such that fluid may be supplied to fill the flowpath from the fluid reservoir via the fluid supply tube (optionally via means for supply flow regulation) while fluid is aspirated by a device through the fluid offtake tube (optionally or as necessary via means for aspirate flow regulation).

Preferably any such apparatus is an automated, programmable system which can cleanse the wound irrigant and/or wound exudate with minimal supervision.

The present invention in this aspect provides several advantages.

One is that application of an irrigant to a wound under simultaneous aspiration creates a wound environment that is exposed to the continuous beneficial effects of both aspects of the therapy for wound healing, as opposed to the sequential intermittent application of irrigant flow and aspiration in known aspirating and/or irrigating apparatus. The latter result in less than optimum performance of the body's own tissue healing processes, and slower healing and/or weaker tissue growth that does not have a strong three-dimensional structure adhering well to and growing from the wound bed. This is a significant disadvantage, in particular in chronic wounds.

Thus, the use of the apparatus of this first aspect of the present invention for aspirating, irrigating and/or cleansing wounds retains and enhances the beneficial effects of aspiration in respect of wound healing by continuous and preferably constant aspiration. These include removing materials deleterious to wound healing with the wound exudate, reducing bacterial load, combating peri-wound oedema and encouraging the formation of wound bed granulation tissue.

Preferred embodiments of the apparatus of this first aspect of the present invention for aspirating, irrigating and/or cleansing chronic wounds apply a milder negative pressure than in conventional negative pressure therapy (which is too aggressive for the fragile tissues of many such wounds). This leads to increased patient comfort, and lessens the risk of inflammation of the wound.

The removal of wound exudate in a given time period of application of the total irrigate and/or aspirate therapy will normally be more effective and/or faster than with a conventional sequential intermittent aspiration and/or irrigation therapy.

Even more desirably, since simultaneous aspiration and irrigation is applied to the wound, wound exudate and materials deleterious to wound healing (such as bacteria and debris, and iron II and iron III and for chronic wounds proteases) will not pool on the wound bed and hinder wound healing, especially in a highly exuding wound. This is especially important in chronic wounds.

The resulting mixed exudate-irrigant fluid will usually be of relatively lower viscosity.

Because simultaneous aspiration and irrigation of the wound provides continuous removal at a constant relatively high speed, the fluid it does not have to be accelerated cyclically from rest, and will be easier to shift than with known forms of aspiration and/or irrigation therapy systems with a conventional sequential aspirate – irrigate – dwell cycle.

This will thus exert a greater net effect on the removal of adherent bacteria and debris.

This is especially the case in those embodiments of the apparatus of this first aspect of the present invention for aspirating, irrigating and/or cleansing wounds where there is an inlet manifold (as described in further detail hereinafter).

This covers and contacts most of the wound bed with openings that deliver the fluid directly to the wound bed over an extended area.

It will be seen that the balance of fluid between fluid aspirated from the wound and irrigant supplied to the wound from the fluid reservoir may provide a predetermined steady state concentration equilibrium of materials beneficial in promoting wound healing over the wound bed. Simultaneous aspiration of wound fluid and irrigation at a controlled flow rate aids in the attainment and maintenance of this equilibrium

The present form of aspiration and/or irrigation therapy systems thus creates a wound environment for better distribution of
materials that are beneficial in some therapeutic aspect, in particular to wound healing, that are present in a wound, but may not be well distributed in the wound, e.g. in a highly exuding wound. (These include cytokines, enzymes, growth factors, cell matrix components, biological signalling molecules and other physiologically active components of the exudate.) and/or
materials in the irrigant that are potentially or actually beneficial in respect of wound healing, such as those noted below in this regard, e.g. growth factors and other physiologically active materials. These may aid wound cell proliferation and new tissue growth that has a strong three-dimensional structure adhering well to and growing from the wound bed. This is a significant advantage, in particular in chronic wounds.

This is especially the case in those embodiments of the apparatus of this first aspect of the present invention for aspirating, irrigating and/or cleansing wounds where there is an inlet manifold as described above.

Simultaneous aspiration and irrigation of the wound provides advantages over topical bolus delivery, such as the pooled delivery of fluid to the wound bed by the application of a conventional sequential aspirate – irrigate – dwell cycle. These include (in addition to greater bioavailability to all areas of the wound surface as above), prolonged delivery between dressing changes and optimal dosing.

In the latter case, sequentially irrigating and aspirating a wound means the need to flood the wound with one or more static fluid physiologically active component in higher dosage concentration than is necessary to achieve a therapeutically active level of such actives on the wound bed.

This is just to maintain a desired average therapeutically active level of such actives on the wound bed during the dwell time period of sequentially irrigating and aspirating a wound, since these dosage concentrations levels tend to drop during this dwell time period in the cycle.

It will be seen that normally the level of such actives is effectively reduced to zero by the conventional sequential subsequent aspiration of the wound.

Less desirably, it has been observed that some of such physiologically active components, for example factors such as TGFβ show different effects at high and low concentrations. An unnecessarily high dose to ensure activity during the residence between typical bolus applications in conventional sequential irrigation - aspiration of the wound may result in less than optimum dosing and performance of the body's own tissue healing processes.

Even less desirably, some of such physiologically active components may have adverse effects at higher concentrations. An unnecessarily high dose to ensure activity during the residence between typical bolus applications in conventional sequential operation may result in undesirable effects on the wound bed.

All of this may result in slow healing and/or slowing down of the healing and growth lacking a strong three-dimensional structure adhering well to and growing from the wound bed. This is a significant disadvantage, in particular in chronic wounds.

Some embodiments of the apparatus of this first aspect of the present invention for aspirating, irrigating and/or cleansing wounds with supply to the wound bed under a positive pressure may be advantageous.

Application of a positive pressure to the wound under the backing layer may make it possible to flood the tissue underlying the wound with one or more physiologically active components in therapeutically active amounts, to promote greater wound healing than by treatment with static fluid physiologically active component(s) alone or by sequential intermittent application of irrigant flow and aspiration

The prolonged delivery of such physiologically active components in therapeutically active amounts in a precise and time-controlled manner by simultaneous aspiration and irrigation, together with

a) the removal of materials deleterious to wound healing from wound exudate,
b) without substantially diluting materials that are beneficial in promoting wound healing in contact with the wound bed, and
c) the continuously supply and recirculation of such materials to the wound,

promotes greater wound healing than

i) by treatment with the fluid physiologically active component(s) alone, or
ii) by topical bolus delivery in known aspirating and irrigating apparatus.

The supply of physiologically active materials may be effected at any appropriate point for this purpose along the apparatus flow path. It is often convenient to effect such supply to the wound via the fluid passing through the wound dressing from irrigant in the fluid reservoir that contains them.

Thus, one embodiment of the apparatus for irrigating, cleansing and/or aspirating wounds of the present invention is characterised in that it comprises an irrigant fluid in the fluid reservoir which in turn comprises one or more physiologically active components in amounts to promote wound healing.

Examples of such components (however supplied) include:
autologous, allogeneic or xenogeneic blood or blood products, such as platelet lysates, plasma or serum.

natural purified proteins or recombinant-produced protein growth factors, such as platelet derived growth factor (PDGF), vascular endothelial growth factor (VEGF), transforming growth factor alpha (TGFα) or transforming growth factor beta (TGFβ-1, 2 or 3), basic-fibroblast growth factor (b-FGF also known as FGF2), epidermal growth factor (EGF), granulocyte-macrophage colony-stimulating factor (GM-CSF); insulin like growth factor-1 (IGF-1) and keratinocyte growth factor 2 KGF2 (also known as FGF7);
natural purified proteins or recombinant produced protein cytokines such as the interleukin 1β (IL1β), or interleukin 8 (IL-8) and
other physiologically active agents whether present normally in acute or chronic wounds, that can be augmented in the irrigant fluid to be of benefit to the wound bed, when such therapy is applied, and combinations thereof.

An additional embodiment of the apparatus for irrigating, cleansing and/or aspirating wounds of the present invention is characterised in the physiologically active components in amounts to promote wound healing comprise materials that are beneficial in promoting wound healing by removing materials or by regulating, limiting or inhibiting processes deleterious to wound healing from wound exudate.

Examples of such materials include
natural purified proteins or recombinant-produced protein, proteinase inhibitors, such as tissue inhibitors of metalloproteinases (TIMP 1 to 4) and alpha 1-antitrypsin (AAT), aprotinin, α-2-macroglogulin;
antibodies or chemically synthesised molecules at inappropriate levels that inhibit or inactivate processes or materials deleterious to wound healing from wound exudate, such as matrix metalloproteinases (MMPs), neutrophil elastase, inhibitors of new blood vessel formation (angiogenesis) such as thrombospondin or kallistatin and combinations thereof.

The irrigant may alternatively or additionally, where appropriate, deliver a steady supply of natural purified proteins or recombinant-produced protein debriding agents to remove and limit eschar, necrotic cells and tissues from the wound bed. Examples of such include stretoptokinase, plasmin, trypsin, collagenases, and other selective proteases or fibrinolytic factors and combinations thereof.

The irrigant supplied to the wound dressing, optionally under a positive pressure on the wound bed, may alternatively or additionally, where appropriate, contain
antioxidants, such as ascorbic acid or stable derivatives thereof and
free radical scavengers, such as gutathione or natural purified proteins or recombinant-produced proteins such as superoxide dismutase (SOD) or
free radical generators (such as hydrogen peroxide) to balance the oxidative stress and oxidant potential of the wound bed in order to maximise the opportunity for wound healing.

The irrigant supplied to the wound dressing under a negative or positive pressure on the wound bed may alternatively or additionally, where appropriate, contain nutrients for wound cells to aid proliferation or migration or the synthesis of matrix components or factors beneficial to wound healing, such as sugars, amino acids, purines, pyrimidines, vitamins, metal ions or minerals, or any such ingredients that may be found in either serum containing or serum-free cell culture medium or might be used as nutritional supplements.

The irrigant supplied to the wound dressing under a negative or positive pressure on the wound bed may alternatively or additionally, where appropriate, contain medicaments, such as antimicrobials, examples of which include antibacterial agents, for example triclosan, iodine, metronidazole, cetrimide, chlorhexidine acetate; antifungal agents, for example sodium undecylenate, chlorhexidine, iodine or clotrimoxazole; antibiotics such as ciprofloxacin or clindamycin.

The irrigant supplied to the wound dressing under a negative or positive pressure on the wound bed may alternatively or additionally, where appropriate, include local analgesics/anaesthetics, such as lignocaine, bupivicaine, or diclofenac to reduce wound pain or pain associated with the dressing:

The irrigant supplied to the wound dressing under a negative or positive pressure on the wound bed may alternatively or additionally, where appropriate supply materials to achieve the delivery of nucleic acid molecules as active genes or gene-containing vectors (DNA, RNA or modified versions thereof), as naked molecules, molecules complexed with nucleic acid binding carriers, molecules within liposomes or as virus vectors to give steady, measured delivery of gene therapeutic molecules to wound bed cells.

The means for supply flow regulation may be a regulator, such as a rotary valve. This is connected between two parts of a fluid supply tube, such that the desired supply flow regulation is achieved.

If there are two or more inlet pipes, these may be connected to a single fluid supply tube with a single regulator, or to first, second, etc. fluid supply tubes, respectively having a first regulator, a second regulator, etc., e.g. a valve or other control device for admitting fluids into the wound.

The means for aspirate flow regulation may be may be similarly provided in a form in which concomitant aspirate flow regulation is possible. It may be a regulator, such as a valve or other control device, e.g. a rotary valve.

Multiple offtake tubes may be similarly provided with single or multiple regulators, all for aspiration of fluids from the apparatus, e.g. to a waste reservoir, such as a collection bag.

It may be desired to apply a negative pressure to the wound. This may be effected by means of a device for moving fluid through the wound applied to the aspirate in the fluid offtake tube downstream of and away from the wound dressing.

Operation may e.g. be carried out at a negative pressure of up to 50%atm., typically at a low negative pressure of up to 20% atm., more usually up to 10% atm. at the wound, as is described hereinafter.

Alternatively, it may be desired to apply a positive pressure to the wound. Operation may e.g. be carried out at a positive pressure of up to 50%atm., typically at a low positive pressure of up to 20% atm., more usually up to 10% atm. at the wound, as is described hereinafter.

This may be effected by means of a device for moving fluid through the wound applied to the fluid in the fluid supply tube upstream of and towards the wound dressing.

The higher end of these ranges are potentially more suitable for hospital use, where relatively high % pressures and/or vacua may be used safely under professional supervision.

The lower end is potentially more suitable for home use, where relatively high % pressures and/or vacua cannot be used safely without professional supervision, or for field hospital use.

In each case, the pressure on the wound may be held constant throughout the desired length of therapy, or may be varied cyclically in a desired positive or negative pressure regime.

A combination of

a) a device for moving fluid through the wound applied to the aspirate in the fluid offtake tube downstream of and away from the wound dressing, and

b) a device for moving fluid through the wound applied to the fluid in the fluid supply tube upstream of and towards the wound dressing,

may be used to apply an overall positive or negative, or even zero pressure to the wound.

At least one body in the flow path to, over and from the wound bed should have sufficient resilience against the pressure to allow any significant compression or decompression of the fluid occur.

Thus, examples of suitable bodies include those which are or are defined by a film, sheet or membrane.

These include inlet or offtake and/or tubes and structures such as bags, chambers and pouches, filled with irrigant fluid, and e.g. the backing layer of the wound dressing, made of elastically resilient thermoplastic materials.

It will be seen that the balance of fluid between aspirated fluid from the wound and irrigant supplied to the wound from the fluid reservoir will thus be largely determined by a means for providing simultaneous aspiration and irrigation of the wound which is a system comprising:

a) means for aspirate flow regulation and/or a device for moving fluid through the wound applied to the aspirate in the fluid offtake tube downstream of and away from the wound dressing, and

b) means for supply flow regulation and/or a device for moving fluid through the wound applied to the fluid in the fluid supply tube upstream of and towards the wound dressing,

The same means may be used to apply an overall positive or negative, or even zero pressure to the wound.

The appropriate flow rate through the supply tube will depend on a number of factors, such as
the components of the irrigant and/or wound exudate, the relative volumes of irrigant and wound exudate, the viscosity of the each of the irrigant, exudate and mixed exudate-irrigant fluid,
whether the dressing is under any negative or positive pressure, and the level of such pressure on the wound bed,
the depth and/or capacity of the wound and
the power consumption needed for a given desired fluid volume flow rate of irrigant and/or wound exudate through the wound.

The dressing may comprise an inlet manifold (as described in further detail hereinafter) that covers and contacts most of the wound bed with openings that deliver the fluid directly to the wound bed over an extended area, in the form of one or more inflatable hollow bodies defined by a film sheet or membrane.

The (usually small) positive pressure above atmospheric from the irrigation device when both devices are running together should be sufficient to inflate the manifold.

The desired fluid volume flow rate of irrigant and/or wound exudate is preferably that for optimum performance of the wound healing process.

The flow rate will usually be in the range of 1 to 1500 ml/hr, such as 5 to 1000 ml/hr, e.g. 15 to 300 ml/hr, such as 35 to 200 ml/hr through the supply tube. The flow rate through the wound may be held constant throughout the desired length of therapy, or may be varied cyclically in a desired flow rate regime.

In practice, the offtake rate of flow of total irrigant and/or wound exudate will be of the order of 1 to 2000, e.g. 35 to 300 ml/24 hr/cm^2, where the cm^2 refers to the wound area, depending on whether the wound is in a highly exuding state.

In practice, the rate of exudate flow is only of the order of up to 75 microlitres / cm^2/ hr (where cm^2 refers to the wound area), and the fluid can be highly mobile or not, depending on the level of proteases present). Exudate levels drop and consistency changes as the wound heals, e.g. to a level for the same wound that equates to 12.5 – 25 microlitres / cm^2 / hr.

It will be seen that the aspirated fluid from the wound will typically contain a preponderance of irrigant from the fluid reservoir over wound exudate.

The necessary adjustments to maintain the desired balance of fluid by means of

a) the means for aspirate flow regulation and/or downstream device, and
b) the means for supply flow regulation and/or upstream device for moving fluid

will be apparent to the skilled person.

The type and/or capacity of

a suitable first device for moving fluid through the wound applied to the aspirate in the fluid offtake tube downstream of and away from the wound dressing and/or

a suitable second device for moving fluid through the wound applied to the irrigant in the fluid supply tube upstream of and towards the wound dressing and/or

will be largely determined by

a) the appropriate or desired fluid volume flow rate of irrigant and/or wound exudate from the wound, and

b) whether it is appropriate or desired to apply a positive or negative pressure to the wound bed, and the level of such pressure to the wound bed

for optimum performance of the wound healing process, and by factors such as portability, power consumption and isolation from contamination.

Where the first device is applied to the fluid in the fluid tube and/or the fluid in the fluid offtake tube downstream of and away from the wound dressing, it will usually apply negative pressure (i.e. below-atmospheric pressure or vacuum) to the wound bed.

The first device for moving fluid through the wound will often be a pump of any of the following types, or a piped supply of vacuum, applied to the aspirate in the fluid offtake tube downstream of and away from the wound dressing.

It may have means for aspirate flow regulation, such as a regulator, such as a rotary valve connected between two parts of a fluid offtake tube, such that the desired supply flow regulation is achieved.

The following types of pump may be used as the first device:

reciprocating pumps, such as piston pumps - where pistons pump fluids through check valves, in particular for positive and/or negative pressure on the wound bed; and

diaphragm pumps - where pulsations of one or two flexible diaphragms displace liquid with check valves.

and
rotary pumps, such as:
progressing cavity pumps - with a cooperating screw rotor and stator, in particular for higher-viscosity and particulate-filled exudate; and
vacuum pumps - with pressure regulators.

The first device may be a diaphragm pump, e.g. preferably a small portable diaphragm pump. This is a preferred type of pump, in order in particular to reduce or eliminate contact of internal surfaces and moving parts of the pump with (chronic) wound exudate, and for ease of cleaning.

Where the pump is a diaphragm pump, and preferably a small portable diaphragm pump, the one or two flexible diaphragms that displace liquid may each be, for example a polymer film, sheet or membrane, that is connected to means for creating the pulsations. This may be provided in any form that is convenient, inter alia as a piezoelectric transducer, a core of a solenoid or a ferromagnetic integer and coil in which the direction of current flow alternates, a rotary cam and follower, and so on.

Where the second device is applied to the fluid in the fluid supply tube upstream of and towards the wound dressing, it will usually apply positive pressure (i.e. above-atmospheric pressure) to the wound bed.

The second device for moving fluid through the wound will often be a pump of any of the following types applied to the irrigant in the fluid supply tube upstream of and towards the wound dressing.

It may have means for aspirate flow regulation, such as a regulator, such as a rotary valve connected between two parts of a fluid offtake tube, such that the desired supply flow regulation is achieved.

The following types of pump may be used as the second device:
reciprocating pumps, such as
shuttle pumps - with an oscillating shuttle mechanism to move fluids at rates from 2 to 50 ml per minute

and
rotary pumps, such as:
centrifugal pumps
flexible impeller
pumps - where elastomeric impeller traps fluid between impeller blades and a moulded housing that sweeps fluid through the pump housing.

peristaltic pumps - with peripheral rollers on rotor arms acting on a flexible fluid aspiration tube to urge fluid current flow in the tube in the direction of the rotor.

rotary vane pumps - with rotating vaned disk attached to a drive shaft moving fluid without pulsation as it spins. The outlet can be restricted without damaging the pump.

The second device may be a peristaltic pump, e.g. preferably a small portable peristaltic pump. This is a preferred type of pump, in order in particular to reduce or eliminate contact of internal surfaces and moving parts of the pump with irrigant, and for ease of cleaning.

Where the pump is a peristaltic pump, this may be e.g. an Instech Model P720 miniature peristaltic pump, with a flow rate: of 0.2 – 180ml/hr and a weight of < 0.5 k. This is potentially useful for home and field hospital use.

Each such pump of any these types may also suitably be one that is capable of pulsed, continuous, variable and/or automated and/or programmable fluid movement. Less usually and less preferably, each such pump of any these types will be reversible.

Preferably simultaneous aspiration and irrigation of the wound may be achieved by having two types of pump as referred to above.

However, it will be apparent to the skilled person that the apparatus of this first aspect of the present invention for aspirating, irrigating and/or cleansing wounds can provide simultaneous aspiration and irrigation of the wound with
a single device for moving fluid through the wound

applied to the aspirate in the fluid offtake tube downstream of and away from the wound dressing or
applied to the irrigant in the fluid supply tube upstream of and towards the wound dressing
in combination with
means for supply flow regulation, connected to a fluid supply tube, and
means for aspirate flow regulation, connected to a fluid offtake tube.

More usually the device for moving fluid through the wound is applied to the aspirate in the fluid offtake tube downstream of and away from the wound dressing, rather than applied to the irrigant.

Examples of suitable and preferred devices include those types of pump that are so described hereinbefore in relation to the first device. This may be a diaphragm pump, e.g. preferably a small portable diaphragm pump. This is a preferred type of pump, in order in particular to reduce or eliminate contact of internal surfaces and moving parts of the pump with (chronic) wound exudate, and for ease of cleaning.

The mode of operation of the system will be apparent to the skilled person, but such systems are described in further detail hereinafter in connection with the means for providing simultaneous aspiration and irrigation of the wound.

The operation of a typical apparatus for simultaneous aspiration and irrigation of a wound at a low negative pressure of up to 20% atm., more usually up to 10% atm. at the wound, with two pumps will now be described.

The necessary changes where the mode of operation is at a positive pressure of e.g. up to 15% atm., more usually up to 5% atm. at the wound will be apparent to the skilled person.

Such a typical apparatus for simultaneous aspiration and irrigation of a wound will operate at a low negative pressure of up to 20% atm., more usually up to 10% atm. at the wound.

It comprises means for providing simultaneous aspiration and irrigation of the wound which is a combination of

a) a first device for moving fluid through the wound applied to the aspirate in the fluid offtake tube downstream of and away from the wound dressing, with optional means for aspirate flow regulation, connected to a fluid offtake tube: and

b) a second device for moving fluid through the wound applied to the irrigant in the fluid supply tube upstream of and towards the wound dressing, with optional means for supply flow regulation, connected to a fluid supply tube.

Before starting the apparatus of this first aspect of the present invention for aspirating, irrigating and/or cleansing wounds, the backing layer of the wound dressing is applied over the wound and conformed to the shape of the bodily part in which the wound is to form a relatively fluid-tight seal or closure.

Any means for supply flow regulation, connected to a fluid supply tube, such as a regulator, such as a rotary valve, is usually closed, and any means for aspirate flow regulation, connected to a fluid offtake tube, is opened.

The aspiration pump is started and run to give a negative pressure of up to 50% atm., more usually up to 20% atm. to be applied applies a vacuum to the interior of the dressing and the wound.

The irrigation pump is then started, so that both pumps are running together, and any means for supply flow regulation is opened.

The irrigation pump flow rate and any means for fluid supply regulation are then adjusted to maintain the desired balance of fluid at a controlled nominal flow rate.

The apparatus is then run for the desired length of therapy and with the desired positive or negative pressure regime.

After this period, the irrigation pump is stopped, shortly followed by the aspiration pump.

The operation of a typical apparatus for simultaneous aspiration and irrigation of a wound at a low negative pressure of up to 20% atm., more usually up to 10% atm. at the wound, with one pump will now be described.

That is, an apparatus with
a single device for moving fluid through the wound applied to the aspirate in the fluid offtake tube downstream of and away from the wound dressing, rather than applied to the irrigant.
in combination with
means for supply flow regulation, connected to a fluid supply tube, and
means for aspirate flow regulation, connected to a fluid offtake tube.

Before starting the apparatus of this first aspect of the present invention for aspirating, irrigating and/or cleansing wounds, the backing layer of the wound dressing is applied over the wound and conformed to the shape of the bodily part in which the wound is to form a relatively fluid-tight seal or closure.

The means for supply flow regulation, connected to a fluid supply tube, such as a regulator, such as a rotary valve, is usually closed, and the means for aspirate flow regulation, connected to a fluid offtake tube, is opened.

The aspiration pump is started and run to give a negative pressure of up to 50% atm., more usually up to 20% atm. to be applied applies a vacuum to the interior of the dressing and the wound.

The means for fluid supply regulation is then adjusted to maintain the desired balance of fluid at a controlled nominal flow rate.

The apparatus is then run for the desired length of therapy and with the desired negative pressure regime.

After this period, the aspiration pump is stopped.

In all embodiments of the apparatus of this first aspect of the present invention for aspirating, irrigating and/or cleansing wounds, a particular advantage is the tendency of the wound dressing to conform to the shape of the bodily part to which it is applied.

The wound dressing comprises a backing layer with a wound-facing face which is capable of forming a relatively fluid-tight seal or closure over a wound and
at least one inlet pipe for connection to a fluid supply tube or tube, which passes through and/or under the wound-facing face, and
and at least one outlet pipe for connection to a fluid offtake tube, which passes through and/or under the wound-facing face,
the point at which the or each inlet pipe and the or each outlet pipe passes through and/or under the wound-facing face forming a relatively fluid-tight seal or closure.

The term 'relatively fluid-tight seal or closure' is used herein to indicate one which is fluid- and microbe-impermeable and permits a positive or negative pressure of up to 50% atm., more usually up to 20% atm. to be applied to the wound. The term 'fluid' is used herein to include gels, e.g. thick exudate, liquids, e.g. water, and gases, such as air, nitrogen, etc.

The shape of the backing layer that is applied may be any that is appropriate to aspirating, irrigating and/or cleansing the wound across the area of the wound.

Examples of such include a substantially flat film, sheet or membrane, or a bag, chamber, pouch or other structure of the backing layer, e.g. of polymer film, which can contain the fluid.

The backing layer may be a film, sheet or membrane, often with a (generally uniform) thickness of up to 100 micron, preferably up to 50 micron, more preferably up to 25 micron, and of 10 micron minimum thickness.

Its largest cross-dimension may be up to 500 mm (for example for large torso wounds), up to 100 mm (for example for axillary and inguinal wounds), and up to 200 mm for limb wounds (for example for chronic wounds, such as venous leg ulcers and diabetic foot ulcers.

Desirably the dressing is resiliently deformable, since this may result in increased patient comfort, and lessen the risk of inflammation of a wound.

Suitable materials for it include synthetic polymeric materials that do not absorb aqueous fluids, such as polyolefins, such as polyethylene e.g. high-density polyethylene, polypropylene, copolymers thereof, for example with vinyl acetate and polyvinyl alcohol, and mixtures thereof; polysiloxanes; polyesters, such as polycarbonates; polyamides, e.g. 6-6 and 6 - 10, and hydrophobic polyurethanes.

They may be hydrophilic, and thus also include hydrophilic polyurethanes.

They also include thermoplastic elastomers and elastomer blends, for example copolymers, such as ethyl vinyl acetate, optionally or as necessary blended with high-impact polystyrene.

They further include elastomeric polyurethane, particularly polyurethane formed by solution casting.

Preferred materials for the present wound dressing include thermoplastic elastomers and curable systems.

The backing layer is capable of forming a relatively fluid-tight seal or closure over the wound and/or around the inlet and outlet pipe(s).

However, in particular around the periphery of the wound dressing, outside the relatively fluid-tight seal, it is preferably of a material that has a high moisture vapour permeability, to prevent maceration of the skin around the wound. It may also be a switchable material that has a higher moisture vapour permeability when in contact with liquids, e.g. water, blood or wound exudate. This may, e.g. be a material that is used in Smith & Nephew's Allevyn™, IV3000™ and OpSite™ dressings.

The periphery of the wound-facing face of the backing layer may bear an adhesive film, for example, to attach it to the skin around the wound.

This may, e.g. be a pressure-sensitive adhesive, if that is sufficient to hold the wound dressing in place in a fluid-tight seal around the periphery of the wound-facing face of the wound dressing.

Alternatively or additionally, where appropriate a light switchable adhesive could be used to secure the dressing in place to prevent leakage. (A light switchable adhesive is one the adhesion of which is reduced by photocuring. Its use can be beneficial in reducing the trauma of removal of the dressing.)

Thus, the backing layer may have a flange or lip extending around the proximal face of the backing layer, of a transparent or translucent material (for which it will be understood that materials that are listed above are amongst those that are suitable).

This bears a film of a light switchable adhesive to secure the dressing in place to prevent leakage on its proximal face, and a layer of opaque material on its distal face. To remove the dressing and not cause excessive trauma in removal of the dressing, the layer of opaque material on the distal face of the flange or lip extending around the proximal wound is removed prior to application of radiation of an appropriate wavelength to the flange or lip.

If the periphery of the wound dressing, outside the relatively fluid-tight seal, that bears an adhesive film to attach it to the skin around the wound, is of a material that has a high moisture vapour permeability or is a switchable material, then the adhesive film, if continuous, should also have a high or switchable moisture vapour permeability, e.g. be an adhesive such as used in Smith & Nephew's Allevyn™, IV3000™ and OpSite™ dressings.

Where a vacuum, is applied to hold the wound dressing in place in a fluid-tight seal around the periphery of the wound-facing face of the wound dressing, the wound dressing may be provided with a silicone flange or lip to seal the dressing around the wound. This removes the need for adhesives and associated trauma to the patient's skin.

Where the interior of, and the flow of irrigant and/or wound exudate to and through, the dressing is under any significant positive pressure, which will tend to act at peripheral points to lift and remove the dressing off the skin around the wound.

In such use of the apparatus, it may thus be necessary to provide means for forming and maintaining such a seal or closure over the wound against such positive pressure on the wound, to act at peripheral points for this purpose.

Examples of such means include light switchable adhesives, as above, to secure the dressing in place to prevent leakage.

Since the adhesion of a light switchable adhesive is reduced by photocuring, thereby reducing the trauma of removal of the dressing, a film of a more aggressive adhesive may be used, e.g. on a flange, as above.

Examples of suitable fluid adhesives for use in more extreme conditions where trauma to the patient's skin is tolerable include ones that consist essentially of cyanoacrylate and like tissue adhesives, applied around the edges of the wound and/or the proximal face of the backing layer of the wound dressing, e.g. on a flange or lip.

Further suitable examples of such means include adhesive (e.g. with pressure-sensitive adhesive) and non-adhesive, and elastic and non-elastic straps, bands, loops, strips, ties, bandages, e.g. compression bandages, sheets, covers, sleeves, jackets, sheathes, wraps, stockings and hose, e.g. elastic tubular hose or elastic tubular stockings that are a compressive fit over a limb wound to apply suitable pressure to it when the therapy is applied in this way; and inflatable cuffs, sleeves, jackets, trousers, sheathes, wraps, stockings and hose that are a compressive fit over a limb wound to apply suitable pressure to it when the therapy is applied in this way.

Such means may each be laid out over the wound dressing to extend beyond the periphery of the backing layer of the wound dressing, and as appropriate will be adhered or otherwise secured to the skin around the wound and/or itself and as appropriate will apply compression (e.g. with elastic bandages, stockings) to a degree that is sufficient to hold the wound dressing in place in a fluid-tight seal around the periphery of the wound,

Such means may each be integral with the other components of the dressing, in particular the backing layer.

Alternatively, it may be permanently attached or releasably attached to the dressing, in particular the backing layer, with an adhesive film, for example, or these components may be a Velcro ™, push snap or twist-lock fit with each other.

The means and the dressing may be separate structures, permanently unattached to each other.

In a more suitable layout for higher positive pressures on the wound, a stiff flange or lip extends around the periphery of the proximal face of the backing layer of the wound dressing as hereinbefore defined.

The flange or lip is concave on its proximal face to define a peripheral channel or conduit.

It has a suction outlet that passes through the flange or lip to communicate with the channel or conduit and may be connected to a device for applying a vacuum, such as a pump or a piped supply of vacuum.

The backing layer may be integral with or attached, for example by heat-sealing, to the flange or lip extending around its proximal face.

To form the relatively fluid-tight seal or closure over a wound that is needed and to prevent passage of irrigant and/or exudate under the periphery of the wound-facing face of the wound dressing, in use of the apparatus, the dressing is set on the skin around the wound.

The device then applies a vacuum to the interior of the flange or lip, thus forming and maintaining a seal or closure acting at peripheral points around the wound against the positive pressure on the wound.

With all the foregoing means of attachment, and means for forming and maintaining a seal or closure over the wound, against positive or negative pressure on the wound at peripheral points around the wound, the wound dressing sealing periphery is preferably of a generally round shape, such as an ellipse, and in particular circular.

To form the relatively fluid-tight seal or closure over a wound and around the inlet pipe(s) and outlet pipe(s) at the point at which they pass through and/or under the wound-facing face, the backing layer may be integral with these other components.

The components may alternatively just be a push, snap or twist-lock fit with each other, or adhered or heat-sealed together.

The or each inlet pipe or outlet pipe may be in the form of an aperture, such as a funnel, hole, opening, orifice, luer, slot or port for connection as a female member respectively to a mating end of
a fluid tube and/or fluid supply tube (optionally or as necessary via means for forming a tube, pipe or hose, or nozzle, hole, opening, orifice, luer, slot or port for connection as a male member respectively to a mating end of

a fluid tube and/or fluid supply tube (optionally or as necessary via means for supply flow regulation) or
a fluid offtake tube.

Where the components are integral they will usually be made of the same material (for which it will be understood that materials that are listed above are amongst those that are suitable).

Where, alternatively, they are a push, snap or twist-lock fit, the may be of the same material or of different materials. In either case, materials that are listed above are amongst those that are suitable for all the components.

The or each pipe will generally pass through, rather than under the backing layer. In such case, the backing layer may often have a rigid and/or resiliently inflexible or stiff area to resist any substantial play between the or each pipe and the or each mating tube, or deformation under pressure in any direction.

It may often be stiffened, reinforced or otherwise strengthened by a boss projecting distally (outwardly from the wound) around each relevant tube, pipe or hose, or nozzle, hole, opening, orifice, luer, slot or port for connection to a mating end of a fluid tube and/or fluid supply tube or fluid offtake tube.

Alternatively or additionally, where appropriate the backing layer may have a stiff flange or lip extending around the proximal face of the backing layer to stiffen, reinforce or otherwise strengthen the backing layer.

The wound dressing may not comprise any integer under the backing layer in the wound in use.

However, this may not provide a system to distribute irrigant over a sufficient functional surface area to irrigate the wound at a practical rate to be suitable for use, in particular in chronic wound aspiration and irrigation, with relatively high concentrations of materials that are deleterious to wound healing.

It may be advantageous to provide a system where wound irrigant may be distributed more evenly, or pass in a more convoluted path under the dressing over the wound bed.

Accordingly, one form of the dressing is provided with a 'tree' form of pipes, tubes or tubules that radiate from an inlet manifold to the wound bed to end in apertures and deliver the aspirating fluid directly to the wound bed via the apertures. Similarly, there is an outlet manifold from which tubules radiate and run to the wound bed to end in openings and collect the fluid directly from the wound bed.

The pipes, etc. may radiate regularly or irregularly through the wound in use, respectively from the inlet or outlet manifold, although regularly may be preferred. A more suitable layout for deeper wounds is one in which the pipes, etc. radiate hemispherically and concentrically, to the wound bed.

For shallower wounds, examples of suitable forms of such layout of the pipes, etc. include ones in which the pipes, etc. radiate in a flattened hemiellipsoid and concentrically, to the wound bed.

Other suitable forms of layout of the pipes, etc. include one which have pipes, tubes or tubules extending from the inlet pipe(s) and/or outlet pipe(s) at the point at which they pass through and/or under the wound-facing face of the backing layer to run over the wound bed. These may have a blind bore with perforations, apertures, holes, openings, orifices, slits or slots along the pipes, etc.

These pipes, etc. then effectively form an inlet pipe manifold that delivers the aspirating fluid directly to the wound bed or outlet pipe or collects the fluid directly from the wound respectively.

It does so via the holes, openings, orifices, slits or slots in the tubes, pipes, tubules, etc. over most of the wound bed under the backing layer.

It may be desirable that the tubes, pipes or tubules are resiliently flexible, e.g. elastomeric, and preferably soft, structures with good conformability in the wound and the interior of the wound dressing.

When the therapy is applied in this way, the layout of the tubes, pipes, tubules, etc. may depend on the depth and/or capacity of the wound.

Thus, for shallower wounds, examples of suitable forms of such layout of the tubes, pipes, tubules, etc. include ones that consist essentially of one or more of the tubes, etc in a spiral.

A more suitable layout for deeper wounds when the therapy is applied in this way may be one which comprises one or more of the tubes, etc in a helix or spiral helix.

Other suitable layouts for shallower wounds include one which have blind-bore, perforated inlet pipe or outlet pipe manifolds that aspirate fluid in the wound when the dressing is in use.

One or both of these may be such a form, the other may be, e.g. one or more straight blind-bore, perforated radial tubes, pipes or nozzles.

A preferred form of inlet pipe (or less usually) outlet pipe manifold that delivers the aspirating fluid directly to the wound bed or collects the fluid directly from the wound respectively is one that comprise one or more conformable hollow bodies defined by a film, sheet or membrane, such as a bag, chamber, pouch or other structure, filled with the irrigant (or less usually) aspirate from the wound, passing through perforations, apertures, holes, openings, orifices, slits or slots in the film, sheet or membrane defining the hollow body or hollow bodies.

These may be of small cross-dimension, so that they may then effectively form microperforations, microapertures or pores in a permeable integer, for example the polymer film, sheet or membrane.

This type of manifold for irrigation (more usually) provides the highest uniformity in the flow distribution of irrigant over the wound at a practical rate to be suitable for use, in particular in chronic wound aspiration and irrigation, and hence to provide a system where materials that are beneficial in promoting wound healing, such as growth factors, cell matrix components, and other physiologically active components of the exudate from a wound, are distributed more evenly under the dressing over the wound bed.

This type of manifold for irrigation (more usually) is noted below with regard to wound fillers under the backing layer, since it is a resiliently flexible, e.g. elastomeric, and soft, structure with good conformability to wound shape that is urged by its own resilience against the backing layer to apply gentle pressure on the wound bed, and is therefore also capable of acting as a wound filler. The film, sheet or membrane, often has a (generally uniform) thickness similar to that of films or sheets used in conventional wound dressing backing layers.

Another suitable layout is one in which
an inlet pipe and/or outlet pipe manifold that delivers the aspirating fluid directly to the wound bed or collects the fluid directly from the wound respectively
via inlet and/or outlet tubes, pipes or tubules,
and the inlet manifold and/or outlet manifold is formed by slots in layers permanently attached to each other in a stack, and
the inlet and/or outlet tubes, pipes or tubules are formed by apertures through layers permanently attached to each other in a stack. (In Figure 10a there is shown an exploded isometric view of such a stack, which is non-limiting.)

As also mentioned herein, the backing layer that is applied may be any that is appropriate to the present system of therapy and permits a positive or negative pressure of up to 50% atm., more usually up to 25% atm. to be applied to the wound.

It is thus often a microbe-impermeable film, sheet or membrane, which is substantially flat, depending on any pressure differential on it, and often with a (generally uniform) thickness similar to such films or sheets used in conventional wound dressings, i.e. up to 100 micron, preferably up to 50 micron, more preferably up to 25 micron, and of 10 micron minimum thickness.

The backing layer may often have a rigid and/or resiliently inflexible or stiff area to resist any substantial play between other components that are not mutually integral, and may be stiffened, reinforced or otherwise strengthened, e.g. by a projecting boss.

Such a form of dressing would not be very conformable to the wound bed, and may effectively form a chamber, hollow or cavity defined by a backing layer and the wound bed under the backing layer.

It may be desirable that the interior of the wound dressing conform to the wound bed, even for a wound in a highly exuding state. Accordingly, one form of the dressing is provided with a wound filler under the backing layer.

This is favourably a resiliently flexible, e.g. elastomeric, and preferably soft, structure with good conformability to wound shape.

It is urged by its own resilience against the backing layer to apply gentle pressure on the wound bed.

The wound filler may be integral with the other components of the dressing, in particular the backing layer.

Alternatively, it may be permanently attached to them/it, with an adhesive film, for example, or by heat-sealing, e.g. to a flange or lip extending from the proximal face, so a not to disrupt the relatively fluid-tight seal or closure over the wound that is needed.

Less usually, the wound filler is releasably attached to the backing layer, with an adhesive film, for example, or these components may be a push, snap or twist-lock fit with each other.

The wound filler and the backing layer may be separate structures, permanently unattached to each other.

The wound filler may be or comprise a solid integer, favourably a resiliently flexible, e.g. elastomeric, and preferably soft, structure with good conformability to wound shape.

Examples of suitable forms of such wound fillers are foams formed of a suitable material, e.g. a resilient thermoplastic. Preferred materials for the present wound dressing include reticulated filtration polyurethane foams with small apertures or pores.

Alternatively or additionally, it may be in the form of, or comprise one or more conformable hollow bodies defined by a film, sheet or membrane, such as a bag, chamber, pouch or other structure, filled with a fluid or solid that urges it to the wound shape.

The film, sheet or membrane, often has a (generally uniform) thickness similar to that of films or sheets used in conventional wound dressing backing layers.

That is, up to 100 micron, preferably up to 50 micron, more preferably up to 25 micron, and of 10 micron minimum thickness, and is often resiliently flexible, e.g. elastomeric, and preferably soft.

Such a filler is often integral with the other components of the dressing, in particular the backing layer, or permanently attached to them/it, with an adhesive film, for example, or by heat-sealing, e.g. to a flange

Examples of suitable fluids contained in the hollow body or bodies defined by a film, sheet or membrane include gases, such as air, nitrogen and argon, more usually air, at a small positive pressure above atmospheric; and liquids, such as water, saline.

Examples also include gels, such as silicone gels, e.g. CaviCare™ gel, or preferably cellulosic gels, for example hydrophilic cross-linked cellulosic gels, such as Intrasite ™ cross-linked materials. Examples also include aerosol foams, where the gaseous phase of the aerosol system is air or an inert gas, such as nitrogen or argon, more usually air, at a small positive pressure above atmospheric; and solid particulates, such as plastics crumbs.

Of course, if the backing layer is a sufficiently conformable and/or e.g. an upwardly dished sheet, the backing layer may lie under the wound filler, rather than vice versa.

In this type of layout, in order for the wound filler to urge the wound dressing towards the wound bed, it will usually have to be firmly adhered or otherwise releasably attached to the skin around the wound. This is especially the case in those embodiments where the wound filler and the backing layer are separate structures, permanently unattached to each other.

In such a layout for deeper wounds when the therapy is applied in this way, the means for such attachment may also form and maintain a seal or closure over the wound.

Where the filler is over the backing layer, and the fluid inlet pipe(s) and outlet pipe(s) pass through the wound-facing face of the backing layer, they may run through or around the wound filler over the backing layer.

One form of the dressing is provided with a wound filler under the backing layer that is or comprises a resiliently flexible, e.g. elastomeric, and preferably soft, hollow body defined by a film, sheet or membrane, such as a bag, chamber, pouch or other structure.

It has apertures, holes, openings, orifices, slits or slots, or tubes, pipes, tubules or nozzles. It communicates with at least one inlet or outlet pipe through at least one aperture, hole, opening, orifice, slit or slot.

The fluid contained in the hollow body may then be the aspirating fluid in the apparatus.

The hollow body or each of the hollow bodies then effectively forms an inlet pipe or outlet pipe manifold that delivers the aspirating fluid directly to the wound bed or collects the fluid directly from the wound respectively via the holes, openings, orifices, slits or slots, or the tubes, pipes or hoses, etc. in the film, sheet or membrane.

When the therapy is applied in this way, the type of the filler may also be largely determined by the depth and/or capacity of the wound.

Thus, for shallower wounds, examples of suitable wound fillers as a component of a wound dressing include ones that consist essentially of one or more conformable hollow bodies defining an inlet pipe and/or outlet pipe manifold that delivers the aspirating fluid directly to the wound bed or collects the fluid directly from the wound.

A more suitable wound filler for deeper wounds when the therapy is applied in this way may be one which comprises one or more conformable hollow bodies defined by, for example a polymer film, sheet or membrane, that at least partly surround(s) a solid integer. This may provide a system with better rigidity for convenient handling.

Unless the wound filler under the backing layer effectively forms an inlet pipe or outlet pipe manifold, in order for aspiration and/or irrigation of the wound bed to occur, it is appropriate for one or more bores, channels, conduits, passages, pipes, tubes, tubules and/or spaces, etc. to run from the point at which the fluid inlet pipe(s) and outlet pipe(s) pass through and/or under the wound-facing face of the backing layer through or around the wound filler under the backing layer.

Less usually, the wound filler is an open-cell foam with pores that may form such bores, channels, conduits, passages and/or spaces through the wound filler under the backing layer.

Where the filler is or comprises one or more conformable hollow bodies defined by, for example a polymer film, sheet or membrane, it may be provided with means for admitting fluids to the wound bed under the wound dressing.

These may be in the form of pipes, tubes, tubules or nozzles running from the point at which the fluid inlet pipe(s) and outlet pipe(s) pass through and/or under the wound-facing face of the backing layer through or around the wound filler under the backing layer.

All of the suitable layouts for shallower wounds that comprise blind-bore, perforated inlet pipe or outlet pipe manifolds that aspirate fluid in the wound when the dressing is in use, that are described hereinbefore, may be used under a wound filler under the backing layer.

In brief, suitable layouts include ones where one or both manifolds are annular or toroidal (regular, e.g. elliptical or circular or irregular), optionally with blind-bore, perforated radial tubes, pipes or nozzles, branching from the annulus or torus; and/or
in a meandering, tortuous, winding, zigzag, serpentine or boustrophedic (i.e. in the manner of a ploughed furrow) pattern, or
defined by slots in and apertures through layers attached to each other in a stack.

The inlet and/or outlet tubes, the fluid tube and the fluid supply tube, etc. may be of conventional type, e.g. of elliptical or circular cross-section, and may suitably have a uniform cylindrical bore, channel, conduit or passage throughout their length, and suitably the largest cross-dimension of the bore may be up to 10 mm for large torso wounds, and up to 2 mm for limb wounds.

The tube walls should suitably thick enough to withstand any positive or negative pressure on them, in particular if the volume of irrigant and/or wound exudate from the wound in is increased by continuing addition to it of wound exudate, and/or fluid passing from a cleansing fluid through a selectively permeable integer, for example the polymer film, sheet or membrane of a two-phase system, such as an aspiration and irrigation unit. However, the prime purpose of such tubes is to convey fluid irrigant and exudate through the length of the apparatus flow path, rather than to act as pressure vessels. The tube walls may suitably be at least 25 micron thick.

The bore or any perforations, apertures, holes, openings, orifices, slits or slots along the pipes, etc. or in the hollow body or each of the hollow bodies may be of small cross-dimension.

They may then effectively form a macroscopic and/or microscopic filter for particulates including cell debris and micro-organisms, whilst allowing proteins and nutrients to pass through.

Such tubes, pipes or hoses, etc. through and/or around the filler, whether the latter is a solid integer and/or one or more resiliently flexible or conformable hollow bodies, are described in further detail hereinbefore in connection with the inlet pipe(s) and outlet pipe(s).

The whole length of the apparatus for aspirating, irrigating and/or cleansing wounds should be microbe-impermeable once the wound dressing is over the wound in use.

It is desirable that the wound dressing and the interior of the apparatus for aspirating, irrigating and/or cleansing wounds of the present invention is sterile.

The fluid may be sterilised in the fluid reservoir and/or the rest of the system in which the fluid moves by ultraviolet, gamma or electron beam irradiation. This way, in particular reduces or eliminates contact of internal surfaces and the fluid with any sterilising agent.

Examples of other methods of sterilisation of the fluid also include e.g. the use of

ultrafiltration through microapertures or micropores, e.g. of 0.22 to 0.45 micron maximum cross-dimension, to be selectively impermeable to microbes; and

fluid antiseptics, such as solutions of chemicals, such as chlorhexidine and povidone iodine; metal ion sources, such as silver salts, e.g. silver nitrate; and hydrogen peroxide;

although the latter involve contact of internal surfaces and the fluid with the sterilising agent.

It may be desirable that the interior of the wound dressing, the rest of the system in which the fluid moves, and/or the wound bed, even for a wound in a highly exuding state, are kept sterile after the fluid is sterilised in the fluid reservoir, or that at least naturally occurring microbial growth is inhibited.

Thus, materials that are potentially or actually beneficial in this respect may be added to the irrigant initially, and as desired the amount in increased by continuing addition.

Examples of such materials include antibacterial agents (some of which are listed above), and antifungal agents.

Amongst those that are suitable are, for example triclosan, iodine, metronidazole, cetrimide, chlorhexidine acetate, sodium undecylenate, chlorhexidine and iodine.

Buffering agents, such as potassium dihydrogen phosphate/ disodium hydrogen phosphate. may be added to adjust the pH, as may local analgesics/anaesthetics, such as lidocaine/lignocaine hydrochloride, xylocaine (adrenoline, lidocaine) and/or anti-inflammatories, to reduce wound pain or inflammation or pain associated with the dressing.

In order to combat the deposition of materials in the flow path from the irrigant, a repellent coating may be used at any point or on any integer in the path in direct contact with the fluid, e.g. on the means for providing simultaneous aspiration and irrigation of the wound or any desired tube or pipe.

Examples of coating materials for surfaces over which the aspirating fluid passes include
anticoagulants, such as heparin, and
high surface tension materials, such as PTFE, and polyamides,
which are useful for growth factors, enzymes and other proteins and derivatives.

The apparatus of the invention for aspirating, irrigating and/or cleansing wounds is provided with means for admitting fluids directly or indirectly to the wound under the wound dressing in the form of a fluid supply tube to a fluid reservoir.

The fluid reservoir may be of any conventional type, e.g. a tube, bag (such as a bag typically used for blood or blood products, e.g. plasma, or for infusion feeds, e.g. of nutrients), chamber, pouch or other structure, e.g. of polymer film, which can contain the irrigant fluid.

The reservoir may be made of a film, sheet or membrane, often with a (generally uniform) thickness similar to that of films or sheets used in conventional wound dressing backing layers, i.e. up to 100 micron, preferably up to 50 micron, more preferably up to 25 micron, and of 10 micron minimum thickness, and is often a resiliently flexible, e.g. elastomeric, and preferably soft, hollow body.

In all embodiments of the apparatus the type and material of the tubes throughout the apparatus of the invention for aspirating, irrigating and/or cleansing wounds and the fluid reservoir will be largely determined by their function.

To be suitable for use, in particular on chronic timescales, the material should be non-toxic and biocompatible, inert to any active components, as appropriate of the irrigant from the fluid reservoir and/or wound exudate in the apparatus flow path, and, in any use of a two-phase system aspiration and irrigation unit, of the dialysate that moves into the aspirating fluid in the apparatus.

When in contact with irrigant fluid, it should not allow any significant amounts of extractables to diffuse freely out of it in use of the apparatus.

It should be sterilisable by ultraviolet, gamma or electron beam irradiation and/or with fluid antiseptics, such as solutions of chemicals, fluid- and microbe-impermeable once in use, and flexible.

Examples of suitable materials for the fluid reservoir include synthetic polymeric materials, such as polyolefins, such as polyethylene, e.g. high-density polyethylene and polypropylene.

Suitable materials for the present purpose also include copolymers thereof, for example with vinyl acetate and mixtures thereof. Suitable materials for the present purpose further include medical grade poly(vinyl chloride).

Notwithstanding such polymeric materials, the fluid reservoir will often have a stiff area to resist any substantial play between it and components that are not mutually integral, such as the fluid supply tube towards the wound dressing, and may be stiffened, reinforced or otherwise strengthened, e.g. by a projecting boss.

Materials deleterious to wound healing that are removed include
oxidants, such as free radicals, e.g. peroxide and superoxide;
iron II and iron III;
all involved in oxidative stress on the wound bed;
proteases, such as serine proteases, e.g. elastase and thrombin; cysteine proteases; matrix metalloproteases, e.g. collagenase; and carboxyl (acid) proteases;

endotoxins, such as lipopolysaccharides;
autoinducer signalling molecules, such as homoserine lactone derivatives, e.g. oxo-alkyl derivatives;
inhibitors of angiogenesis such as thrombospondin-1 (TSP-1), plasminogen activator inhibitor, or angiostatin (plasminogen fragment);
pro-inflammatory cytokines such as tumour necrosis factor alpha (TNFα) and interleukin 1 beta (IL-1β),
oxidants, such as free radicals, e.g. , e.g. peroxide and superoxide; and
metal ions, e.g. iron II and iron III, all involved in oxidative stress on the wound bed.

It is believed that aspirating wound fluid aids in removal from of the materials deleterious to wound healing from wound exudate and/or irrigant, whilst distributing materials that are beneficial in promoting wound healing in contact with the wound.

A steady state concentration equilibrium of materials beneficial in promoting wound healing may be set up between in the irrigant and/or wound exudate. Aspirating wound fluid aids in the quicker attainment of this equilibrium

Materials beneficial to wound healing that are distributed include cytokines, enzymes, growth factors, cell matrix components, biological signalling molecules and other physiologically active components of the exudate and/or
materials in the irrigant that are potentially or actually beneficial in respect of wound healing, such as nutrients for wound cells to aid proliferation, gases, such as oxygen.

The conduits through which respectively the irrigant and/or wound exudate passes to and from the wound dressing and

i) preferably have means for modular disconnection and withdrawal of the dressing,

ii) providing an immediate fluid-tight seal or closure over the ends of the conduits and the cooperating tubes in the rest of the apparatus of the invention so exposed,

to prevent continuing passage of irrigant and/or exudate and cleansed fluid, and cleansing fluid.

The outlet from the means for aspirate flow regulation and/or tubes may be collected and monitored and used to diagnose the status of the wound and/or its exudate.

Any waste reservoir may be of any conventional type, e.g. a tube, bag (such as a bag typically used as an ostomy bag), chamber, pouch or other structure, e.g. of polymer film, which can contain the irrigant fluid that has been bled off. In all embodiments of the apparatus, the type and material of the waste reservoir will be largely determined by its function.

To be suitable for use, the material need only be fluid-impermeable once in use, and flexible.

Examples of suitable materials for the fluid reservoir include synthetic polymeric materials, such as polyolefins, such as poly (vinylidene chloride).

Suitable materials for the present purpose also include polyethylene, e.g. high-density polyethylene, polypropylene, copolymers thereof, for example with vinyl acetate and mixtures thereof.

In a second aspect of the present invention there is provided a conformable wound dressing, characterised in that it comprises a backing layer with a wound-facing face which is capable of forming a relatively fluid-tight seal or closure over a wound and has

at least one inlet pipe for connection to a fluid supply tube, which passes through and/or under the wound-facing face, and

at least one outlet pipe for connection to a fluid offtake tube, which passes through and/or under the wound-facing face,

the point at which the or each inlet pipe and the or each outlet pipe passes through and/or under the wound-facing face forming a relatively fluid-tight seal or closure over the wound.
The dressing is advantageously provided for use in a bacteria-proof pouch.

Examples of suitable forms of such wound dressings are as described by way of example hereinbefore.

In a third aspect of the present invention there is provided a method of treating wounds to promote wound healing using the apparatus for aspirating, irrigating and/or cleansing wounds of the present invention.

The present invention will now be described by way of example only with reference to the accompanying drawings in which:

Figure 1 is a schematic view of an apparatus for aspirating, irrigating and/or cleansing a wound according to the first aspect of the present invention that has
a single device for moving fluid through the wound applied to the aspirate in the fluid offtake tube downstream of and away from the wound dressing,
in combination with
means for supply flow regulation, connected to a fluid supply tube, and
means for aspirate flow regulation, connected to a fluid offtake tube.

Figure 2 is a schematic view of another apparatus for aspirating, irrigating and/or cleansing a wound according to the first aspect of the present invention that has
a first device for moving fluid through the wound applied to the aspirate in the fluid offtake tube downstream of and away from the wound dressing, with means for aspirate flow regulation, connected to a fluid offtake tube; and
a second device for moving fluid through the wound applied to the irrigant in the fluid supply tube upstream of and towards the wound dressing.
Figures 3 to 7 are cross-sectional views of conformable wound dressings, of the second aspect of the present invention for aspirating and/or irrigating wounds.

In these, Figures 3a to 6a are cross-sectional plan views of the wound dressings, and Figures 3b to 6b are cross-sectional side views of the wound dressings.

Figures 8 to 10 are various views of inlet and outlet manifold layouts for the wound dressings of the second aspect of the present invention for respectively delivering fluid to, and collecting fluid from, the wound.

Figures 11 and 12 are omitted.

Figures 13 to 26 are cross-sectional views of conformable wound dressings, of the second aspect of the present invention for aspirating and/or irrigating wounds.

Referring to Figure 1, the apparatus (1) for aspirating, irrigating and/or cleansing wounds comprises
a conformable wound dressing (2), having
a backing layer (3) which is capable of forming a relatively fluid-tight seal or closure (4) over a wound (5) and
one inlet pipe (6) for connection to a fluid supply tube (7), which passes through the wound-facing face of the backing layer (5) at (8), and
one outlet pipe (9) for connection to a fluid offtake tube (10), which passes through the wound-facing face at (11),
the points (8), (11) at which the inlet pipe and the outlet pipe passes through and/or under the wound-facing face forming a relatively fluid-tight seal or closure over the wound;
the inlet pipe being connected via means for supply flow regulation, here a valve (14), by the fluid supply tube (7) to a fluid reservoir (12), and
the outlet pipe (9) being connected via means for aspirate flow regulation, here a valve (16) and a fluid offtake tube (10) to waste, e.g. to a collection bag (not shown);
a device for moving fluid through the wound (17), here a diaphragm pump (18), e.g. preferably a small portable diaphragm pump, acting on the fluid aspiration tube (13) to apply a low negative pressure on the wound; and

the valve (14) in the fluid supply tube (7), the valve (16) in the fluid offtake tube (10), and the diaphragm pump (18), providing means for providing simultaneous aspiration and irrigation of the wound (17), such that fluid may be supplied to fill the flowpath from the fluid reservoir via the fluid supply tube (via the means for supply flow regulation) and moved by the device through the flow path.

The operation of the apparatus is as described hereinbefore.

Referring to Figure 2, the apparatus (21) is a variant two-pump system with essentially identical, and identically numbered, components as in Figure 1, except that
there is no means for supply flow regulation in the fluid supply tube (7) from the fluid reservoir (12B), and
there is
a first device for moving fluid through the wound (17), here a diaphragm pump (18A), e.g. preferably a small portable diaphragm pump, acting on the fluid aspiration tube (13) downstream of and away from the wound dressing to apply a low negative pressure on the wound; with
means for aspirate flow regulation here a valve (16) connected to the fluid offtake tube (10) and a vacuum vessel (aspirant collection jar) (12A); and
a second device for moving fluid through the wound (17), here a peristaltic pump (18B), e.g. preferably a small portable diaphragm pump, applied to the irrigant in the fluid supply tube (7) upstream of and towards the wound dressing,
the first device (18A) and second device (18B), and the valve (16) in the fluid offtake tube (10), and the diaphragm pump (18), providing means for providing simultaneous aspiration and irrigation of the wound (17).

The operation of the apparatus is as described hereinbefore
Referring to Figures 3 to 6, each dressing (41) is in the form of a conformable body defined by a microbe-impermeable film backing layer (42) with a uniform thickness of 25 micron, with a wound-facing face (43) which is capable of forming a relatively fluid-tight seal or closure over a wound.

The backing layer (42) extends in use on a wound over the skin around the wound. On the proximal face of the backing layer (43) on the overlap (44), it bears an adhesive film (45), to attach it to the skin sufficiently to hold the wound dressing in place in a fluid-tight seal around the periphery of the wound-facing face (43) of the wound dressing.

There is one inlet pipe (46) for connection to a fluid supply tube (not shown), which passes through and/or under the wound-facing face (43), and one outlet pipe (47) for connection to a fluid offtake tube (not shown), which passes through and/or under the wound-facing face (43),

Referring to Figures 3a and 3b, one form of the dressing is provided with a wound filler (48) under a circular backing layer (42).

This comprises a generally frustroconical, toroidal conformable hollow body, defined by a membrane (49) which is filled with a fluid, here air or nitrogen, that urges it to the wound shape.

The filler (48) may be permanently attached to the backing layer with an adhesive film (not shown) or by heat-sealing.

The inlet pipe (46) and outlet pipe (47) are mounted centrally in the backing layer (42) above the central tunnel (50) of the toroidal hollow body (48) and each passes through the backing layer (42).

Each extends in pipes (51) and (52) respectively through the tunnel (50) of the toroidal hollow body (48) and then radially in diametrically opposite directions under the body (48).

This form of the dressing is a more suitable layout for deeper wounds.
Referring to Figures 4a and 4b, a more suitable form for shallower wounds is shown. This comprises a circular backing layer (42) and a circular upwardly dished first membrane (61) with apertures (62) that is permanently attached to the backing layer (42) by heat-sealing to form a circular pouch (63).

The pouch (63) communicates with the inlet pipe (46) through a hole (64), and thus effectively forms an inlet pipe manifold that delivers the aspirating fluid directly to the wound when the dressing is in use.

An annular second membrane (65) with openings (66) is permanently attached to the backing layer (42) by heat-sealing to form an annular chamber (67) with the layer (42).

The chamber (67) communicates with the outlet pipe (47) through an orifice (68), and thus effectively forms an outlet pipe manifold that collects the fluid directly from the wound when the dressing is in use.

Referring to Figures 5a and 5b, a variant of the dressing of Figures 4a and 4b that is a more suitable form for deeper wounds is shown.

This comprises a circular backing layer (42) and a filler (69), in the form of an inverted frustroconical, solid integer, here a resilient elastomeric foam, formed of a thermoplastic, or preferably a cross-linked plastics foam.

It may be permanently attached to the backing layer (42), with an adhesive film (not shown) or by heat-sealing.

A circular upwardly dished sheet (70) lies under and conforms to, but is a separate structure, permanently unattached to, the backing layer (42) and the solid integer (69).

A circular upwardly dished first membrane (71) with apertures (72) is permanently attached to the sheet (70) by heat-sealing to form a circular pouch (73) with the sheet (70).

The pouch (73) communicates with the inlet pipe (46) through a hole (74), and thus effectively forms an inlet pipe manifold that delivers the aspirating fluid directly to the wound when the dressing is in use.

An annular second membrane (75) with openings (76) is permanently attached to the sheet (70) by heat-sealing to form an annular chamber (77) with the sheet (70).

The chamber (77) communicates with the outlet pipe (47) through an orifice (78), and thus effectively forms an outlet pipe manifold that collects the fluid directly from the wound when the dressing is in use.

Alternatively, where appropriate the dressing may be provided in a form in which the circular upwardly dished sheet (70) functions as the backing layer and the solid filler (69) sits on the sheet (70) as the backing layer, rather than under it. The filler (69) is held in place with an adhesive film or tape, instead of the backing layer (42).

Referring to Figures 6a and 6b, a dressing that is a more suitable form for deeper wounds is shown.

This comprises a circular backing layer (42) and a filler (79), in the form of an inverted generally hemispherical integer, permanently attached to the backing layer with an adhesive film (not shown) or by heat-sealing.
Here it is a resilient elastomeric foam or a hollow body filled with a fluid, here a gel that urges it to the wound shape.

The inlet pipe (46) and outlet pipe (47) are mounted peripherally in the backing layer (42).

A circular upwardly dished sheet (80) lies under and conforms to, but is a separate structure, permanently unattached to, the backing layer (42) and the filler (79).

A circular upwardly dished bilaminate membrane (81) has a closed channel (82) between its laminar components, with
perforations (83) along its length on the outer surface (84) of the dish formed by the membrane (81) and
an opening (85) at the outer end of its spiral helix, through which the channel (82) communicates with the inlet pipe (46),

and thus effectively forms an inlet pipe manifold that delivers the aspirating fluid directly to the wound when the dressing is in use.

The membrane (81) also has apertures (86) between and along the length of the turns of the channel (82).

The inner surface (87) of the dish formed by the membrane (81) is permanently attached at its innermost points (88) with an adhesive film (not shown) or by heat-sealing to the sheet (80). This defines a mating closed spirohelical conduit (89).

At the outermost end of its spiral helix, the conduit (89) communicates through an opening (90) with the outlet pipe (47) and is thus effectively an outlet manifold to collect the fluid directly from the wound via the apertures (86).

Referring to Figures 7a and 7b, one form of the dressing is provided with a circular backing layer (42).

A first (larger) inverted hemispherical membrane (92) is permanently attached centrally to the layer (42) by heat-sealing to form a hemispherical chamber (94) with the layer (42).

A second (smaller) concentric hemispherical membrane (93) within the first is permanently attached to the layer (42) by heat-sealing to form a hemispherical pouch (95).

The pouch (95) communicates with the inlet pipe (46) and is thus effectively an inlet manifold, from which pipes (97) radiate hemispherically and run to the wound bed to end in apertures (98). The pipes (97) deliver the aspirating fluid directly to the wound bed via the apertures (98).

The chamber (94) communicates with the outlet pipe (47) and is thus effectively an outlet manifold from which tubules (99) radiate hemispherically and run to the wound bed to end in openings (100). The tubules (99) collect the fluid directly from the wound via the openings (100).

Referring to Figures 8a to 8d, one form of the dressing is provided with a square backing layer (42) and
first tube (101) extending from the inlet pipe (46), and
second tube (102) extending from the outlet pipe (47)
at the points at which they pass through the backing layer, to run over the wound bed.

These pipes (101), (102) have a blind bore with orifices (103), (104) along the pipes (101), (102). These pipes (101), (102) respectively form an inlet pipe or outlet pipe manifold that delivers the aspirating fluid directly to the wound bed or collects the fluid directly from the wound respectively via the orifices.

In Figures 8a and 8d, one layout of each of the pipes (101), (102) as inlet pipe and outlet pipe manifolds is a spiral.

In Figure 8b, the layout is a variant of that of Figures 8a and 8b, with the layout of the inlet manifold (101) being a full or partial torus, and the outlet manifold (102) being a radial pipe.

Referring to Figure 8c, there is shown another suitable layout in which the inlet manifold (101) and the outlet manifold (102) run alongside each other over the wound bed in a boustrophedic pattern, i.e. in the manner of ploughed furrows.

Referring to Figures 9a to 9d, there are shown other suitable layouts for deeper wounds, which are the same as shown in Figures 8a to 8d. The square backing layer (42) however has a wound filler (110) under, and may be permanently attached to, the backing layer (42), with an adhesive film (not shown) or by heat-sealing.

The filler (110) is an inverted hemispherical solid integer, here a resilient elastomeric foam, formed of a thermoplastic, preferably a cross-linked plastics foam.

Under the latter is a circular upwardly dished sheet (111) which conforms to, but is a separate structure, permanently unattached to, the solid filler (110). Through the sheet (111) pass the inlet pipe (46) and the outlet pipe (47), to run over the wound bed. These pipes (101), (102) again have a blind bore with orifices (103), (104) along the pipes (101), (102).

Alternatively (as in Figures 5a and 5b), where appropriate the dressing may be provided in a form in which the circular upwardly dished sheet (111) functions as the backing layer and the solid filler (110) sits on the sheet (42) as the backing layer, rather than under it. The filler (110) is held in place with an adhesive film or tape, instead of the backing layer (42).

In Figures 10a to 10c, inlet and outlet manifolds for the wound dressings for respectively delivering fluid to, and collecting fluid from, the wound, are formed by slots in and apertures through layers permanently attached to each other in a stack.

Thus, in Figure 10a there is shown an exploded isometric view of an inlet manifold and outlet manifold stack (120) of five square coterminous thermoplastic polymer layers, being first to fifth layers (121) to (125), each attached with an adhesive film (not shown) or by heat-sealing to the adjacent layer in the stack (120).

The topmost (first) layer (121) (which is the most distal in the dressing in use) is a blank square capping layer.

The next (second) layer (122), shown in Figure 10b out of the manifold stack (120), is a square layer, with an inlet manifold slot (126) through it. The slot (126) runs to one edge (127) of the layer (122) for connection to a mating end of a fluid inlet tube ((not shown), and spreads into four adjacent branches (128) in a parallel array with spaces therebetween.
The next (third) layer (123) is another square layer, with inlet manifold apertures (129) through the layer (123) in an array such that the apertures (129) are in register with the inlet manifold slot (126) through the second layer (122) (shown in Figure 10b).

The next (fourth) layer (124), shown in Figure 10c out of the manifold stack (120), is another square layer, with inlet manifold apertures (130) through the layer (124) in an array such that the apertures (130) are in register with the apertures (129) through the third layer (123).

It also has an outlet manifold slot (131) through it.

The slot (131) runs to one edge (132) of the layer (124) on the opposite side of the manifold stack (120) from the edge (127) of the layer (122), for connection to a mating end of a fluid outlet tube (not shown).

It spreads into three adjacent branches (133) in a parallel array in the spaces between the apertures (130) in the layer (124) and in register with the spaces between the apertures (129) in the layer (122).

The final (fifth) layer (125) is another square layer, with inlet manifold apertures (134) through the layer (125) in an array such that the apertures (134) are in register with the inlet manifold apertures (130) through the fourth layer (124) (in turn in register with the apertures (129) through the third layer (123). It also has outlet manifold apertures (135) in the layer (125) in an array such that the apertures (135) are in register with the outlet manifold slot (131) in the fourth layer (124).

It will be seen that, when the layers (121) to (125) are attached together to form the stack (120), the topmost (first) layer (121), the inlet manifold slot (126) through the second layer (122), and the third layer (123) cooperate to form an inlet manifold in the second layer (122), which is in use is connected to a mating end of a fluid inlet tube (not shown).

The inlet manifold slot (126) through the second layer (122), and the inlet manifold apertures (129), (130) and (134) through the layers (123), (124) and (125), all being mutually in register, cooperate to form inlet manifold conduits though the third to fifth layers (123), (124) and (125) between the

inlet manifold in the second layer (122) and the proximal face (136) of the stack (120).

The third layer (121), the outlet manifold slot (131) through the fourth layer (124), and the fifth layer (125) cooperate to form an outlet manifold in the fourth layer (124), which is in use is connected to a mating end of a fluid outlet tube (not shown).

The outlet manifold slot (131) through the fourth layer (124), and the outlet manifold apertures (135) through the fifth layer (125), being mutually in register, cooperate to form outlet manifold conduits though the fifth layer (125) between the outlet manifold in the fourth layer (124) and the proximal face (136) of the stack (120).

Referring to Figures 13 to 15, these forms of the dressing are provided with a wound filler (348) under a circular backing layer (342).
This comprises respectively a generally downwardly domed or toroidal, or oblately spheroidal conformable hollow body, defined by a membrane (349) which is filled with a fluid, here air or nitrogen, that urges it to the wound shape.

The filler (348) is permanently attached to the backing layer via a boss (351), which is e.g. heat-sealed to the backing layer (342).

An inflation inlet pipe (350), inlet pipe (346) and outlet pipe (347) are mounted centrally in the boss (351) in the backing layer (342) above the hollow body (348). The inflation inlet pipe (350) communicates with the interior of the hollow body (348), to permit inflation of the body (348). The inlet pipe (346) extends in a pipe (352) effectively through the hollow body (348). The outlet pipe (347) extends radially immediately under the backing layer (342).

In Figure 13, the pipe (352) communicates with an inlet manifold (353), formed by a membrane (361) with apertures (362) that is permanently attached to the filler (348) by heat-sealing.

It is filled with foam (363) formed of a suitable material, e.g. a resilient thermoplastic. Preferred materials include reticulated filtration polyurethane foams with small apertures or pores.

In Figure 14, the outlet pipe (347) communicates with a layer of foam (364) formed of a suitable material, e.g. a resilient thermoplastic. Again, preferred materials include reticulated filtration polyurethane foams with small apertures or pores.

In all of Figures 13, 14 and 15, in use, the pipe (346) ends in one or more openings that deliver the irrigant fluid directly from the wound bed over an extended area.

Similarly, the outlet pipe (347) effectively collects the fluid radially from the wound periphery when the dressing is in use.

Referring to Figure 16, the dressing is also provided with a wound filler (348) under a circular backing layer (342).

This also comprises a generally toroidal conformable hollow body, defined by a membrane (349) which is filled with a fluid, here air or nitrogen, that urges it to the wound shape.

The filler (348) may be permanently attached to the backing layer (342) via a first boss (351) and a layer of foam (364) formed of a suitable material, e.g. a resilient thermoplastic. Again, preferred materials include reticulated filtration polyurethane foams with small apertures or pores.

The first boss (351) and foam layer (364) are respectively heat-sealed to the backing layer (342) and the boss (351).

An inflation inlet pipe (350), inlet pipe (346) and outlet pipe (347) are mounted centrally in the first boss (351) in the backing layer (342) above the toroidal hollow body (348).

The inflation inlet pipe (350), inlet pipe (346) and outlet pipe (347) respectively each extend in a pipe (353), (354) and (355) through a central tunnel (356) in the hollow body (348) to a second boss (357) attached to the toroidal hollow body (348).

The pipe (353) communicates with the interior of the hollow body (348), to permit inflation of the body (348). The pipe (354) extends radially through the second boss (357) to communicate with an inlet manifold (352), formed by a membrane (361).

This is permanently attached to the filler (348) by heat-sealing in the form of a reticulated honeycomb with openings (362) that deliver the irrigant fluid directly to the wound bed over an extended area.

The pipe (355) collects the fluid flowing radially from the wound centre when the dressing is in use.

This form of the dressing is a more suitable layout for deeper wounds

In Figure 17, the dressing is similar to that of Figure 16, except that the toroidal conformable hollow body, defined by a membrane (349), is filled with a fluid, here a solid particulates, such as plastics crumbs or beads, rather than a gas, such as air or an inert gas, such as nitrogen or argon, and the inflation inlet pipe (350) and pipe (353) are omitted from the central tunnel (356).

Examples of contents for the body (348) also include gels, such as silicone gels or preferably cellulosic gels, for example hydrophilic cross-linked cellulosic gels, such as Intrasite ™ cross-linked materials. Examples also include aerosol foams, and set aerosol foams, e.g. CaviCare™ foam.

Referring to Figures 18 and 19, another form for deeper wounds is shown. This comprises a circular backing layer (342) and a lobed chamber (363) in the form of a deeply indented disc much like a multiple Maltese cross or a stylised rose.

This is defined by an upper impervious membrane (361) and a lower porous film (362) with apertures (364) that deliver the irrigant fluid directly from the wound bed over an extended area. A number of configurations of the chamber (363) are shown, all of which are able to conform well to the wound bed by the arms closing in and possibly overlapping in insertion into the wound.

In a particular design of the chamber (363), shown lowermost, on of the arms extended and provided with an inlet port at the end of the extended arm. This provides the opportunity for coupling and decoupling the irrigant supply remote from the dressing and the wound in use.

An inlet pipe (346) and outlet pipe (347) are mounted centrally in a boss (351) in the backing layer (342) above the chamber (363). The inlet pipe (346) is permanently attached to, and communicate with the interior of, the chamber (363), which thus effectively forms an inlet manifold. The space above the chamber (363) is filled with a loose gauze packing (364). .

In Figure 18, the outlet pipe (347) collects the fluid from the interior of the dressing from just under the wound-facing face (343) of the backing layer (342).

A variant of the dressing of Figure 18 is shown in Figure 19. The outlet pipe (347) is mounted to open at the lowest point of the space above the chamber (363) into a piece of foam (374).

In Figure 20, the dressing is similar to that of Figure 13, except that the inlet pipe (352) communicates with an inlet manifold (353), formed by a membrane (361) with apertures (362), over the upper surface of the generally downwardly domed wound hollow filler (348), rather than through it.

In Figure 22, the dressing is similar to that of Figure 14, with the addition of an inlet manifold (353), formed by a membrane (361) with apertures (362), over the lower surface of the generally downwardly domed annular wound hollow filler.

In Figure 21, the generally downwardly domed annular wound hollow filler is omitted.

Referring to Figure 23, another form for deeper wounds is shown. An inlet pipe (346) and outlet pipe (347) are mounted centrally in a boss (351) in the backing layer (342) above a sealed-off foam filler (348).

The inlet pipe (346) is permanently attached to and passes through the filler (348) to the wound bed. The outlet pipe (347) is attached to and communicates with the interior of, a chamber (363) defined by a porous foam attached to the upper periphery of the filler (348). The chamber (363) thus effectively forms an outlet manifold.

In Figure 24, the foam filler (348) is only partially sealed-off. The inlet pipe (346) is permanently attached to and passes through the filler (348) to the wound bed. The outlet pipe (347) is attached to and communicates with the interior of the foam of the filler (348). Fluid passes into an annular gap (349) near the upper periphery of the filler (348) into the foam, which thus effectively forms an outlet manifold.

Figures 25 and 26 show dressings in which the inlet pipe (346) and outlet pipe (347) pass through the backing layer (342).

In Figure 25, they communicates with the interior of a porous bag filler (348) defined by a porous film (369) and filled with elastically resilient plastics bead or crumb.

In Figure 26, they communicate with the wound space just below a foam filler (348). The foam (348) may CaviCare ™ foam, injected and formed in situ around the pipes (346) and (347).

The use of the apparatus of the present invention will now be described by way of example only in the following Example:

<u>Example 1 - Removal of adherent bacteria and debris with a two-pump apparatus.</u>

In this example, a culture medium sheet containing nutritional supplements with an adherent bacterial culture of Staphylococcus aureus on its top surface is laid in a cavity wound model to represent adherent bacteria and debris on a wound bed to be removed by the two-pump apparatus.

The dressing is essentially identical with that in Figure 18, i.e. it comprises a circular backing layer and a lobed chamber in the form of a deeply indented disc much like a multiple Maltese cross or a stylised rose, defined by an upper impervious membrane and a lower porous film with apertures that deliver the irrigant fluid directly from the wound bed over an extended area.

The irrigant supplied to the wound dressing under a negative pressure on the wound bed contains a therapeutically active amount of an antibacterial agent, selected from chlorhexidine, povidone iodine, triclosan, metronidazole, cetrimide and chlorhexidine acetate.

A two-pump system is set up essentially as in Figure 2, with
an irrigant dispensing bottle – 1000ml Schott Duran, connected to
a peristaltic pump (Masterflex) for irrigant delivery, and associated power supply and supply tube,
a diaphragm vacuum pump (Schwarz) for aspiration, and associated power supply and offtake tube, connected to
a vacuum vessel (aspirant collection jar) – Nalgene 150ml polystyrene
each pump being connected to
a dressing consisting of the following elements:

1. wound-contacting element, comprising a lobed bag with low porosity 'leaky' membrane wound contact layer on the lower surface, impermeable film on the top, and a foam spacer between the two layers to allow free flow of irrigant solution.
2. a space filling element, comprising a reticulated, open-cell foam (black reticulated foam, Foam Techniques) 30mm thick, 60mm diameter

3. an occlusive adhesive coated polyurethane backing layer top film (Smith & Nephew Medical) with acrylic pressure sensitive adhesive
4. two tubes passing under the occlusive top film, and sealed to prevent leakage of gas or liquid:
   a. one tube centrally penetrating the top film of the wound-contacting element to deliver irrigant into the chamber formed by this film and the porous element;
   b. the other tube of approximately equal length to remove aspirant with the opening positioned just above the top film of the wound contacting element.

Preparation of agar culture medium sheet with adherent Staphylococcus aureus culture (This is a species that gives you whatever results you need.):

An aqueous solution of agar culture medium is prepared by weighing agar culture medium containing nutritional supplements into a glass jar and making it up to the required weight with deionised water. The jar is placed in an oven (Heraeus), at a set temperature. After 60 minutes the jar is removed from the oven and shaken, to encourage mixing.

Petri dishes are partially filled with 10g quantities of the culture medium and placed in a fridge (LEC, set temperature: 4°C) to set for at least 1 hour.

Final thickness of the culture medium sheet is ~5mm. Petri dishes containing the culture medium sheet are removed from the fridge at least 2 hours before use. The culture medium sheet in the Petri dishes is then inoculated with Staphylococcus aureus.

Each is then placed in an incubator at a set temperature.

After the culture has covered more than 50% of the agar surface the dishes are removed from the incubator.

They are place in a fridge, and removed from the fridge at least 2 hours before use.

Preparation of test equipment and materials

Irrigant solution (deionised water containing a therapeutically effective amount of an antibacterial agent, selected from chlorhexidine, povidone iodine, triclosan, metronidazole, cetrimide and chlorhexidine acetate) and the Perspex wound model are pre-conditioned in an oven (Gallenkamp) at set temperature 37°C, for at least 4 hours before use.

For each test, a freshly prepared culture medium sheet with adherent Staphylococcus aureus culture is removed from a Petri dish and weighed. The Perspex wound model is then removed from the oven and the culture medium sheet with adherent Staphylococcus aureus culture placed at the bottom of the cavity. Application of the dressing to the wound model is as follows:

- the wound contacting element is carefully placed over the culture medium sheet with adherent Staphylococcus aureus culture
- the foam filler is placed on top of this with the irrigant and aspirant tubes running centrally to the top of the cavity (the foam filler is slit to the centre to facilitate this).
- the side entry port, pre-threaded onto the tubes, is adhesively bonded to the upper surface of the wound model block using an acrylic pressure sensitive adhesive
- the top adhesive coated film is applied over all of the elements and pressed down to give a seal on all sides, and especially around the tube entry/exit point

Application of the dressing to the wound model is the same for all tests performed. All tubing used is the same for each experiment (e.g. material, diameter, length).

Simultaneous Irrigation & Aspiration

For the experiment most of the apparatus (not including the pumps, power supply, and connecting tubing to and from the pumps) is placed in an oven (Gallenkamp, set temperature: 37°C), on the same shelf.

Before starting the irrigation pump a vacuum is drawn on the system to check that the dressing and tube connections are substantially airtight.

The pumping system is controlled to give a pressure at the vacuum vessel of approximately -75mmHg before opening the system up to include the dressing). Once system integrity has been confirmed, the irrigation pump is started (nominal flow rate: 50ml/hr), i.e. both pumps running together. Timing of the experiment is started when the advancing water front within the irrigant tube is observed to have reached the top of the dressing.

After 60 minutes, the irrigation pump is stopped, shortly followed by the vacuum (aspiration) pump. Aspirant liquid collected in the vacuum jar is decanted into a glass jar. The vacuum jar is rinsed with ~100ml of deionised water and this added to the same glass jar. The aspirant solution is then assayed for the Staphylococcus aureus quantity present.

Sequential Irrigation & Aspiration

The experimental set up is as for the simultaneous irrigation/aspiration experiment. Before starting the experiment a vacuum is pulled on the system to check that the dressing and tube connections are substantially airtight. The pumping system is controlled to give a pressure at the vacuum vessel of approximately -75mmHg before opening the system up to include the dressing. Once system integrity has been confirmed, the irrigation pump is started (nominal rate: 186ml/hr) and run until the advancing water front in the irrigant tube is observed to have reached the top of the dressing.

The pump is temporarily stopped at this point whilst the vacuum line is sealed (using a tube clamp) and the vacuum pump stopped.

Timing of the experiment is from the point the irrigation pump is restarted. The pump is run until 50ml of irrigant has entered the wound model (just over 16 minutes at the rate of 186ml/hr). At this point the irrigant pump is stopped.

It is observed that during the filling phase of sequential filling and flushing, air trapped in the model wound cavity caused the top film of the dressing to inflate substantially, to a point approaching failure.

After a further ~44 minutes (60 minutes from the start of the experiment) the vacuum pump is started and the tube clamp on the aspirant line removed. The wound model is aspirated for 5 minutes. Towards the end of this period a small leak is introduced into the top film of the dressing to maximise the amount of fluid drawn from the wound model (it is observed that as the pressure differential between the wound model cavity and the vacuum jar reduced to zero, the flow of aspirant also tended to slow. Introducing a small leak re-established the pressure differential and the flow of aspirant out of the cavity).

Aspirant liquid collected in the vacuum jar is decanted into a glass jar. The vacuum jar is rinsed with ~100ml of deionised water and this added to the same glass jar. The aspirant solution is then assayed for the Staphylococcus aureus quantity present.

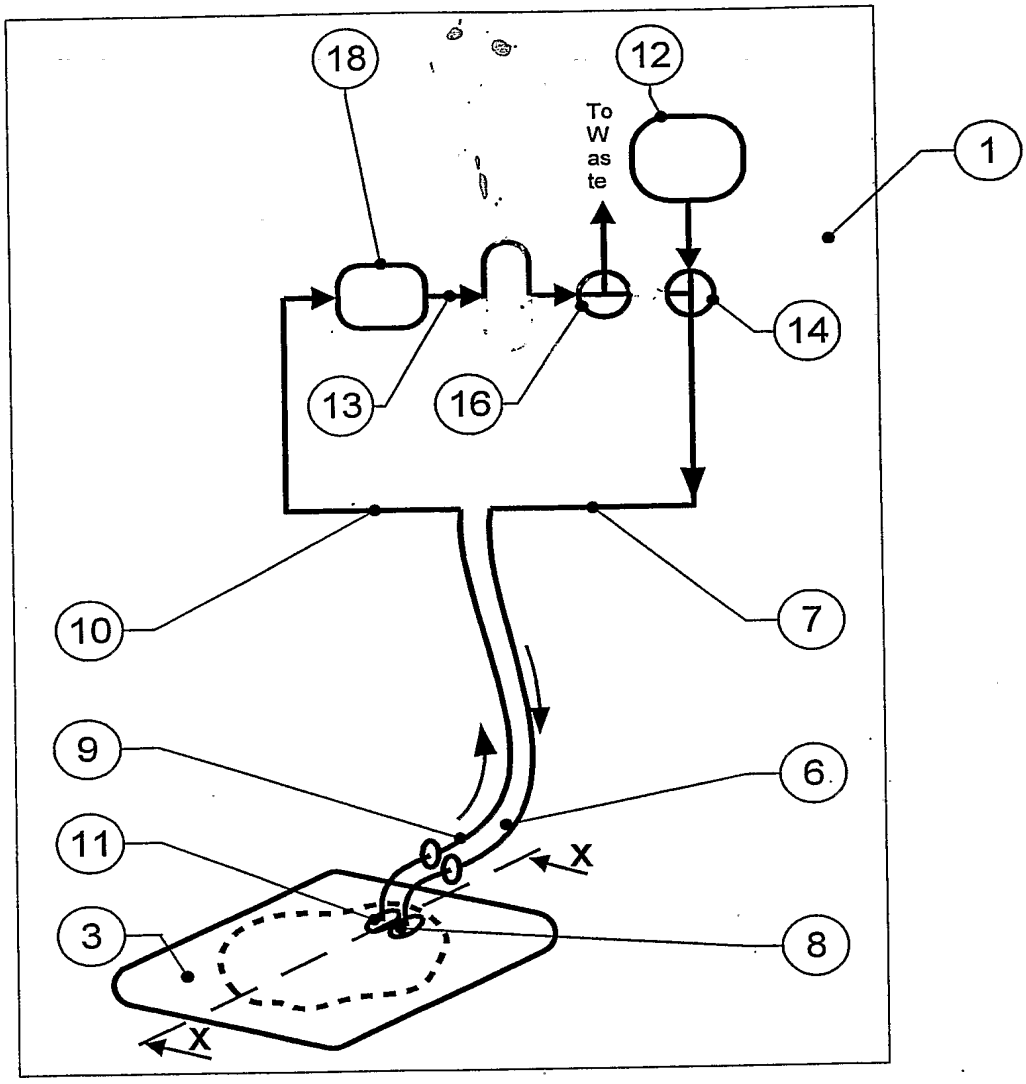
Conclusions

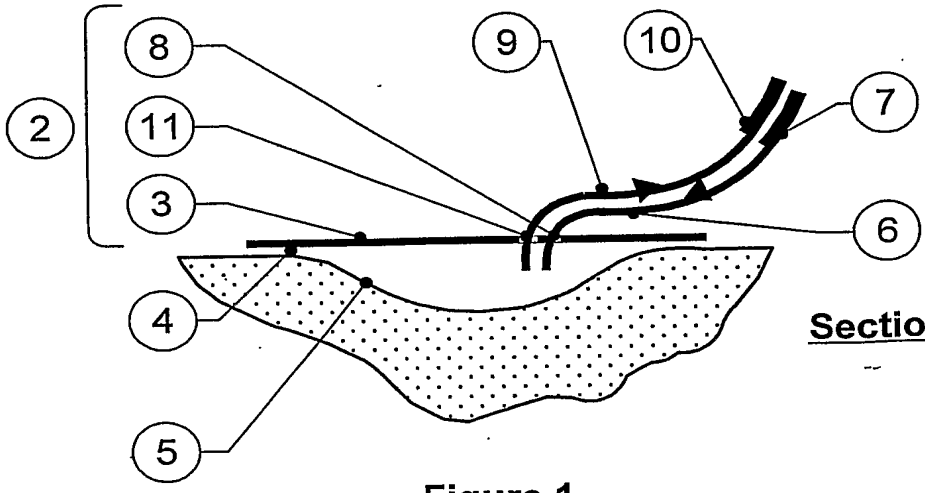
Simultaneously irrigating and aspirating the wound model removes or kills more of the adherent Staphylococcus aureus on the culture medium sheet placed at the base of the wound model cavity than sequentially filling and emptying the cavity, even though the amount of liquid entering the wound and the duration of the experiment are the same in both cases. Simultaneously irrigating and aspirating also removes ore fluid from the model wound.

It is observed that during the filling phase of sequential filling and flushing, air trapped in the model wound cavity caused the top film of the dressing to inflate substantially to a point approaching failure. With the fill/flush cycle it is found necessary to introduce a small leak into the top film to maximise yield of aspirant during the flush cycle (the fall-off in aspiration rate without the hole thought due to the loss in pressure differential between the vacuum vessel and wound model).

Abstract

An apparatus for cleansing wounds in which irrigant fluid containing one or more physiologically active components from a reservoir connected to a conformable wound dressing and wound exudate from the dressing are moved by a device (which may be a single pump or two or more pumps) for moving fluid through a flow path which passes through the dressing and a means for providing simultaneous aspiration and irrigation of the wound. The latter removes materials deleterious to wound healing, while distributing materials that are beneficial in promoting wound healing and the physiologically active components in therapeutically active amounts in a precise and time-controlled manner over the wound bed. The dressing, including one with openings that deliver the irrigant fluid directly to the wound bed over an extended area, and a method of treatment using the apparatus.



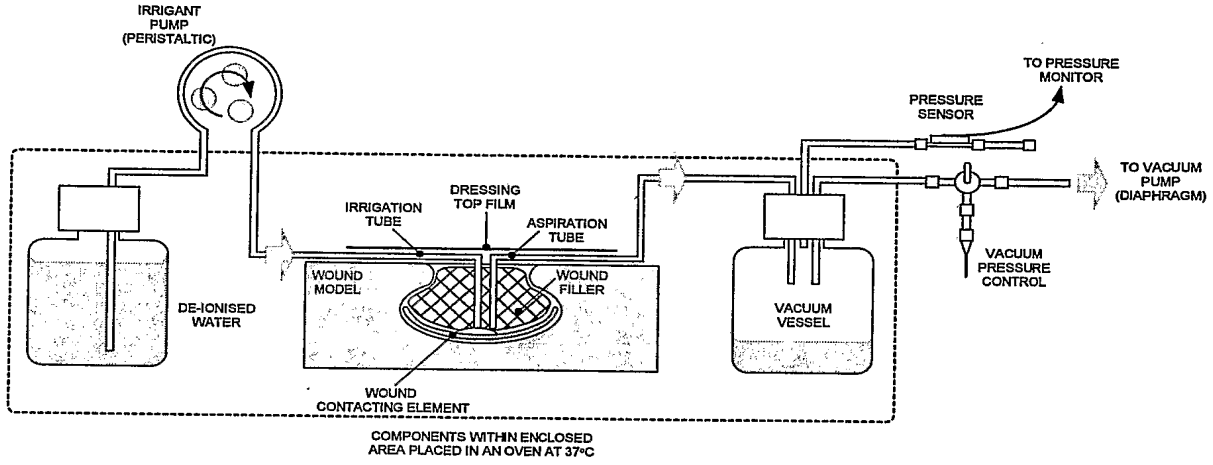


Section View on X-X

Figure 1

Figure 2

5


IRRIGANT PUMP (PERISTALTIC)
TO PRESSURE MONITOR
PRESSURE SENSOR
TO VACUUM PUMP (DIAPHRAGM)
DRESSING TOP FILM
IRRIGATION TUBE
ASPIRATION TUBE
WOUND MODEL
WOUND FILLER
DE-IONISED WATER
VACUUM VESSEL
VACUUM PRESSURE CONTROL
WOUND CONTACTING ELEMENT
COMPONENTS WITHIN ENCLOSED AREA PLACED IN AN OVEN AT 37°C

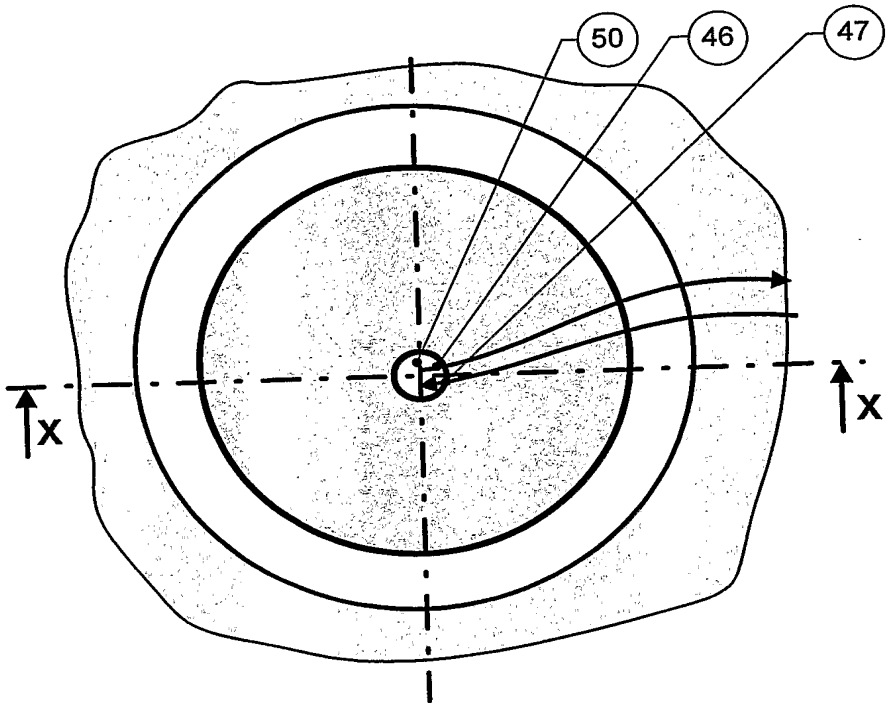


Figure 3a

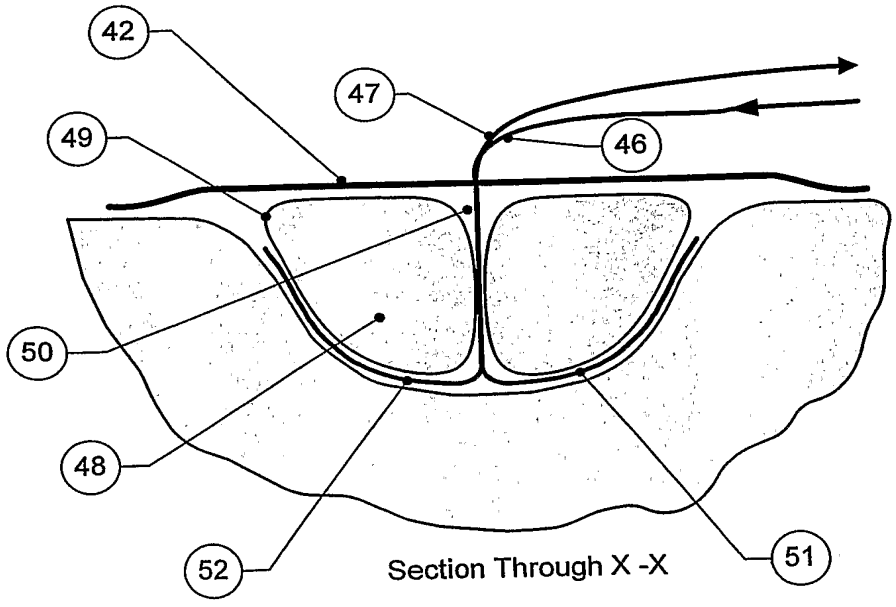


Figure 3b

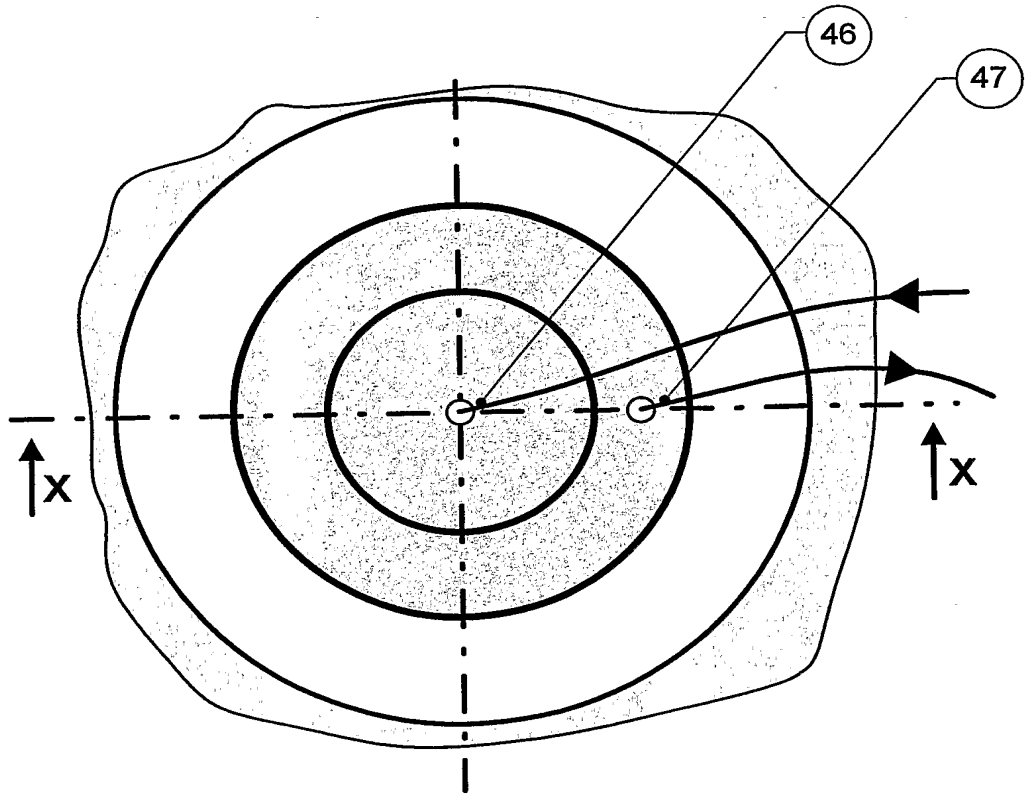


Figure 4a

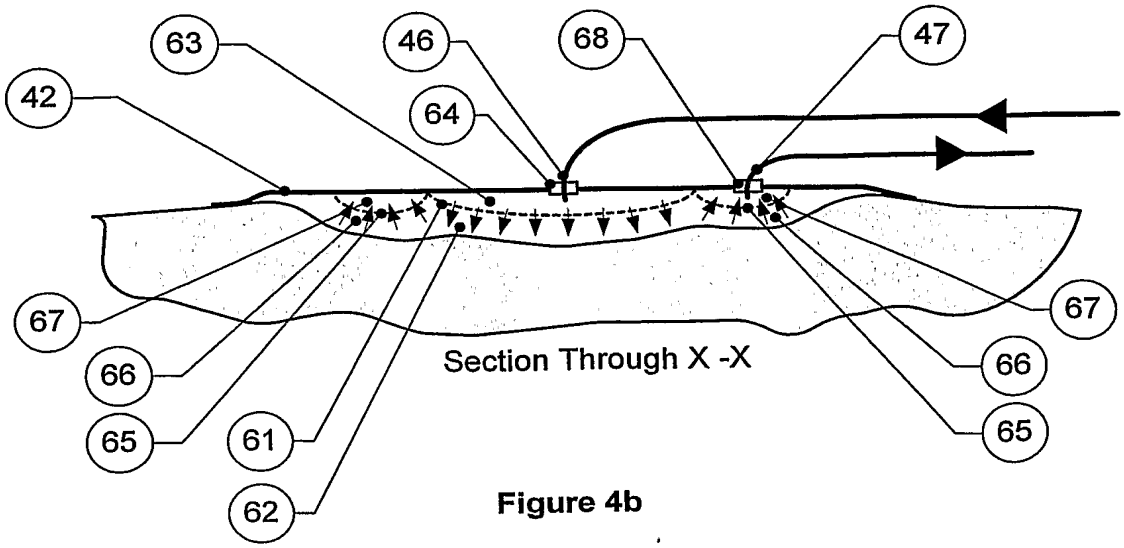


Figure 4b

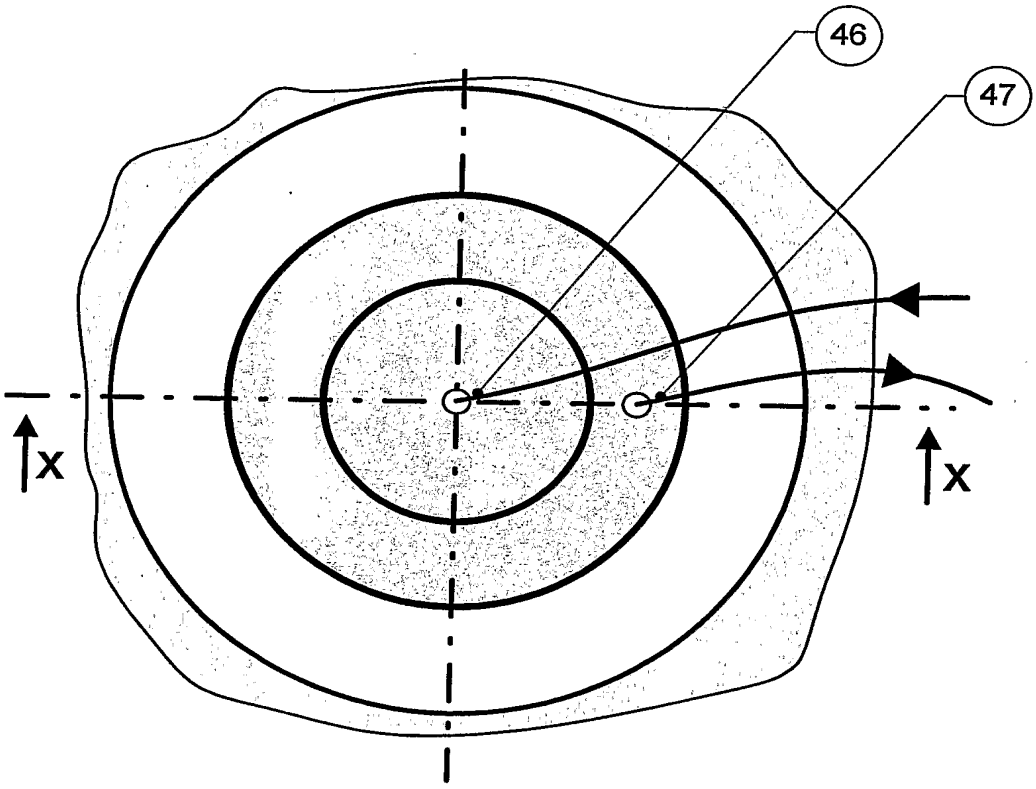
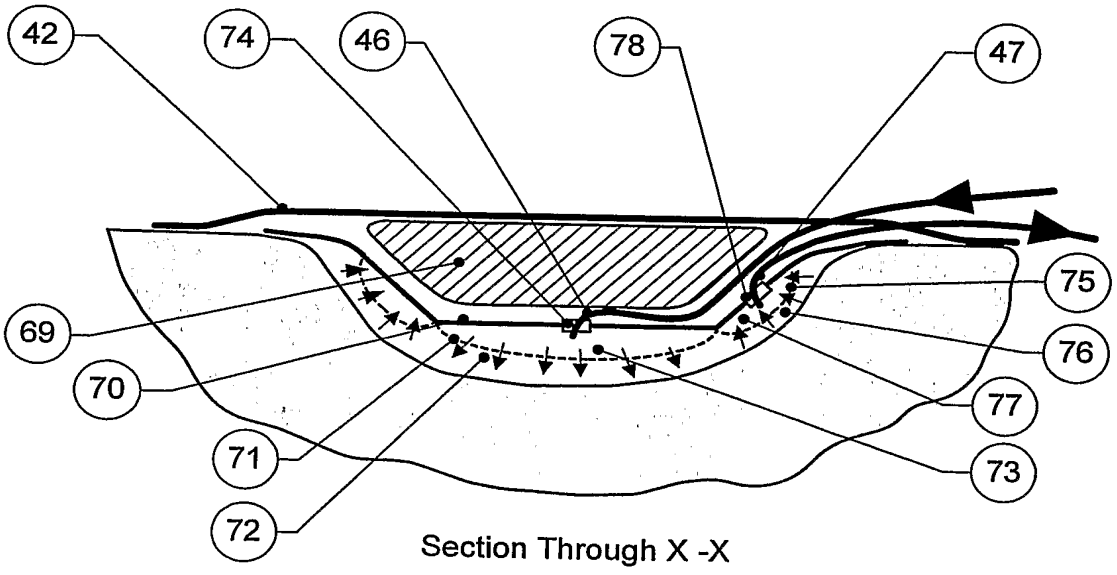


Figure 5a



Section Through X -X

Figure 5b

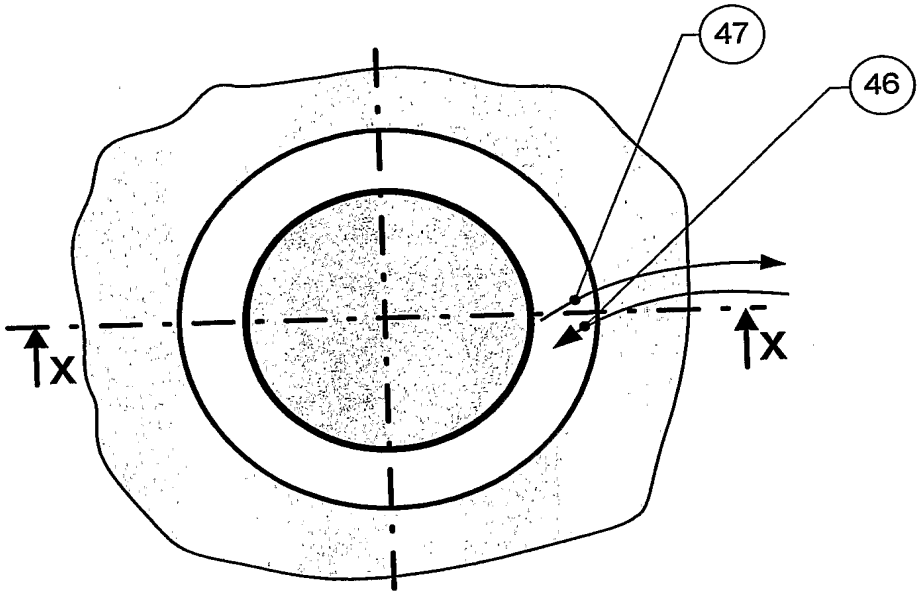


Figure 6a

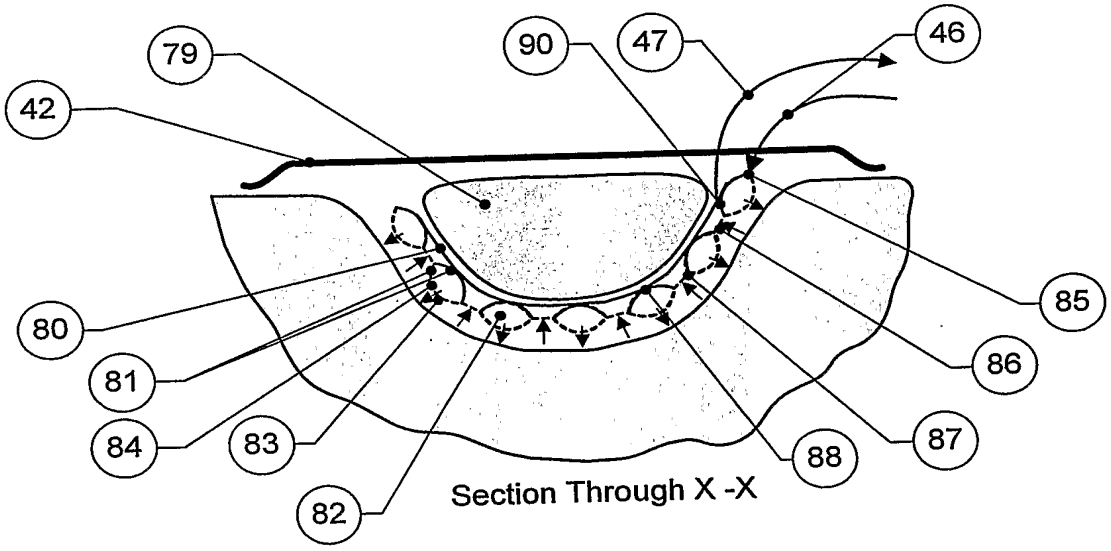


Figure 6b

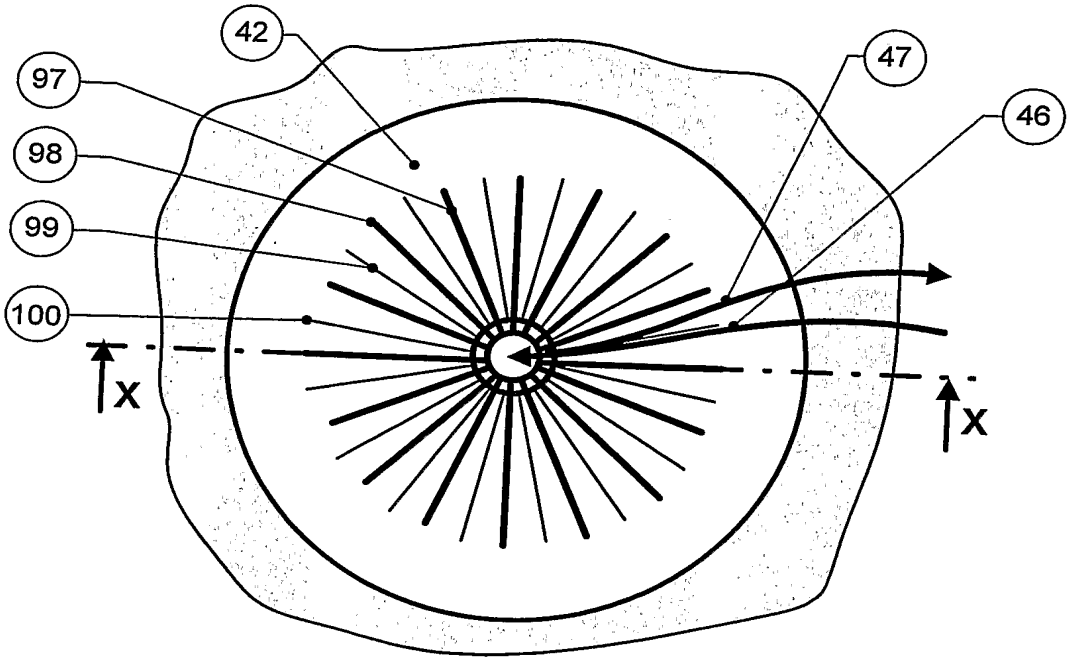
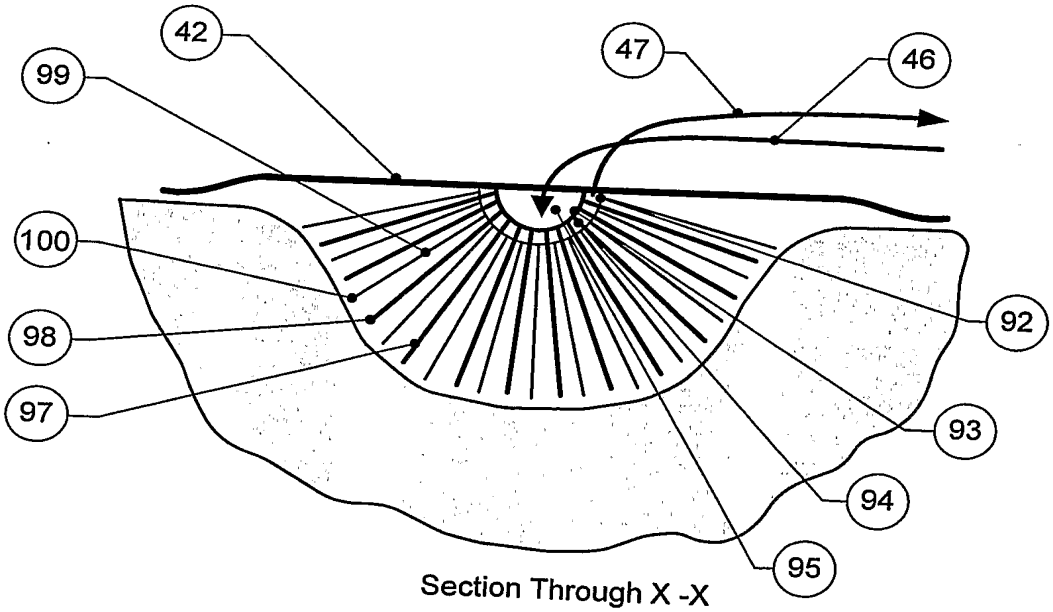


Figure 7a



Section Through X -X

Figure 7b

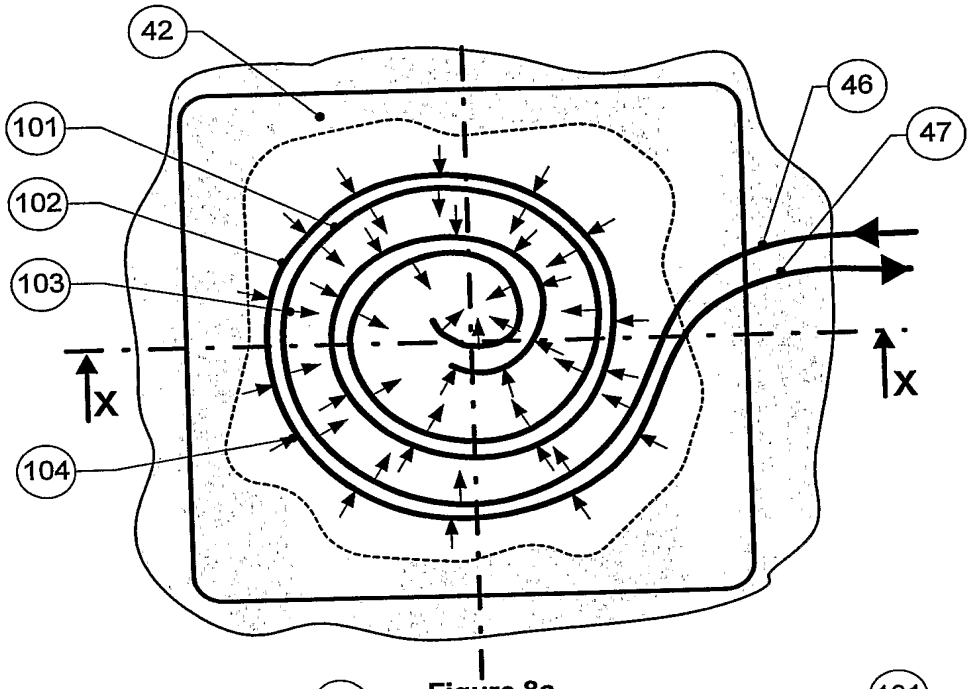


Figure 8a

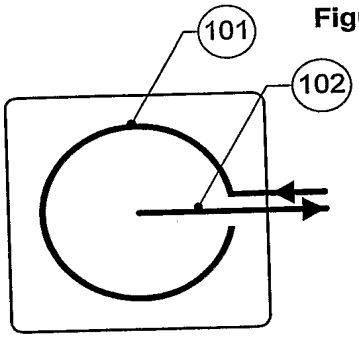


Figure 8b

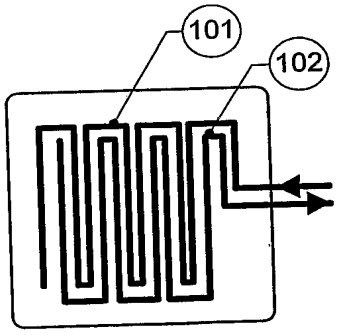
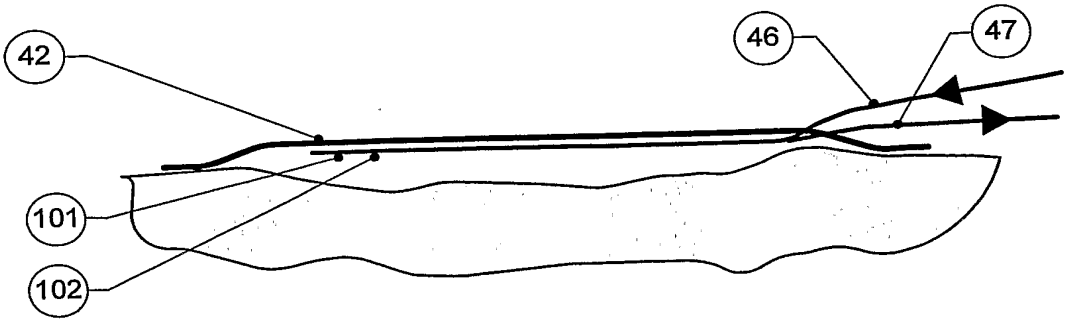


Figure 8c



Section Through X -X

Figure 8d

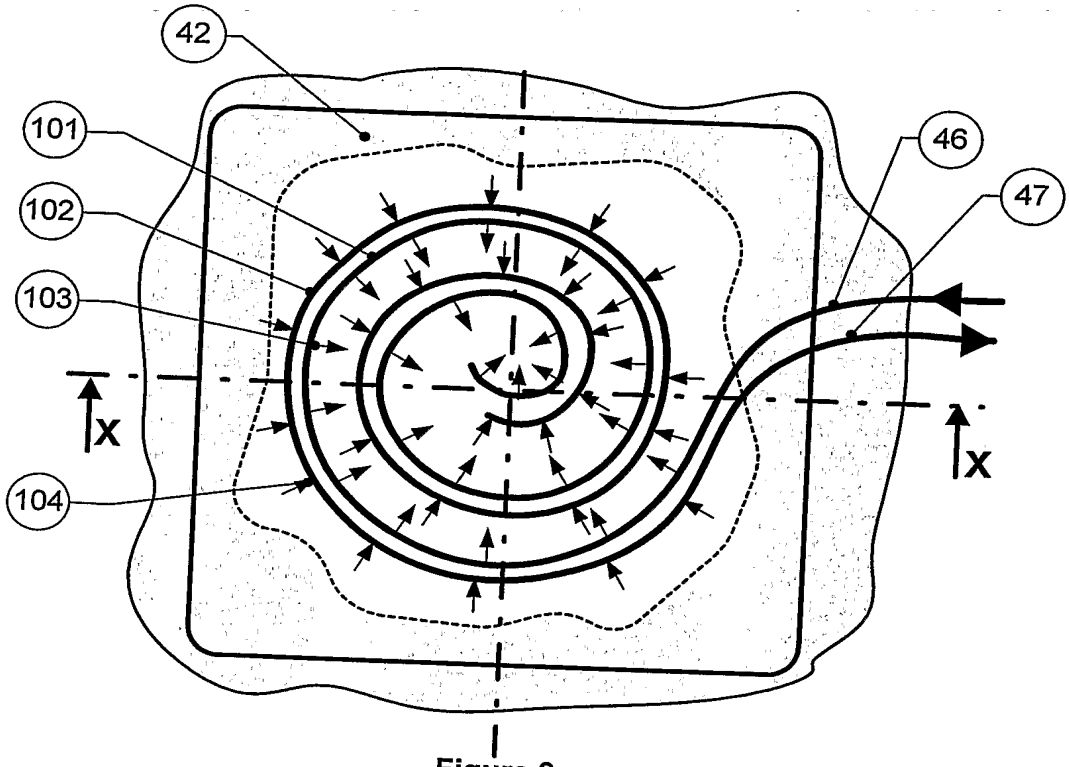
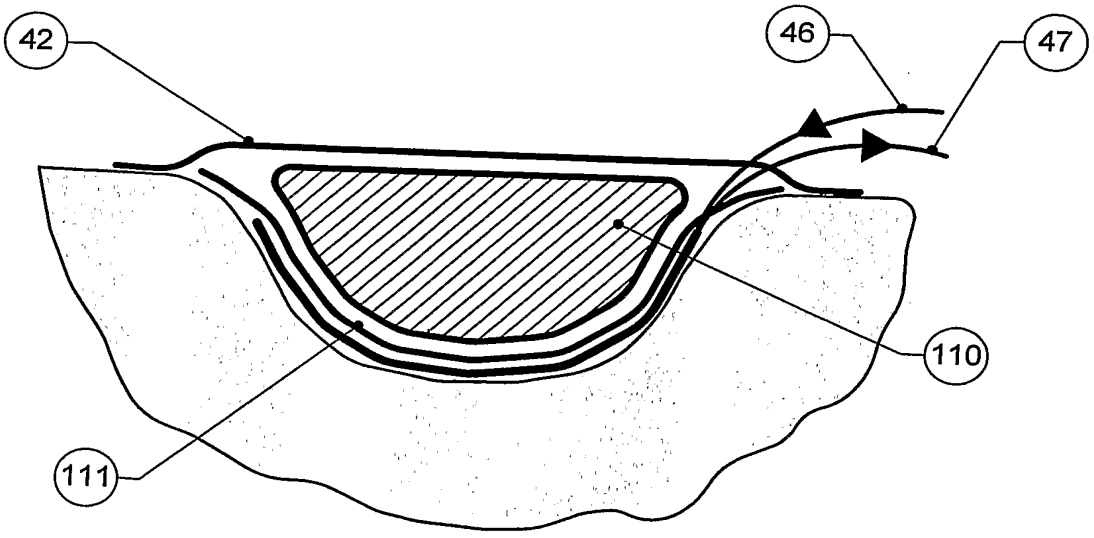


Figure 9a



Section Through X -X

Figure 9b

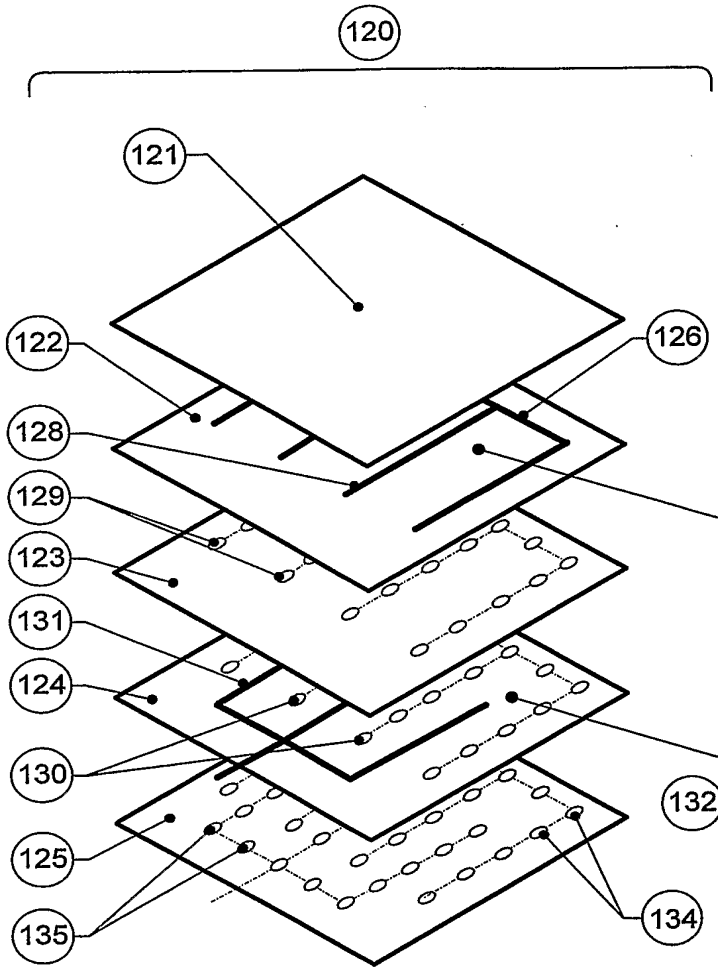
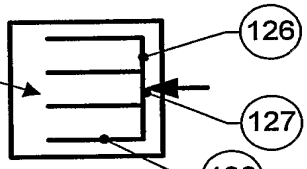


Figure 10a



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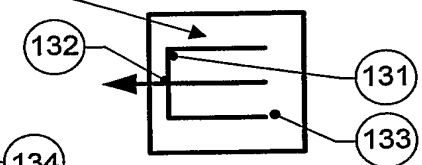

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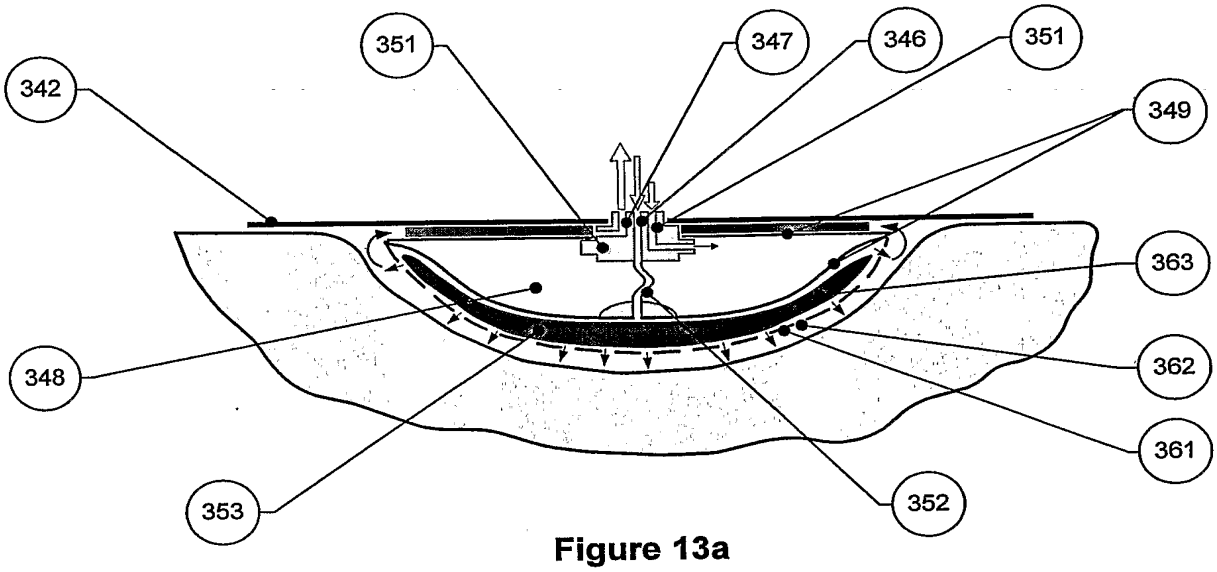

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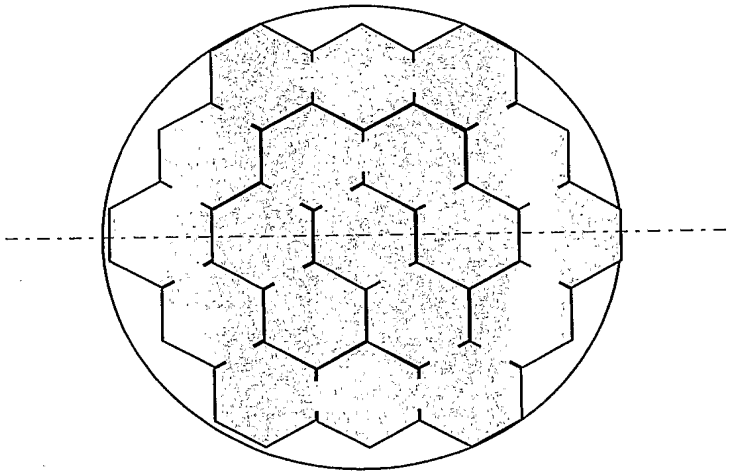

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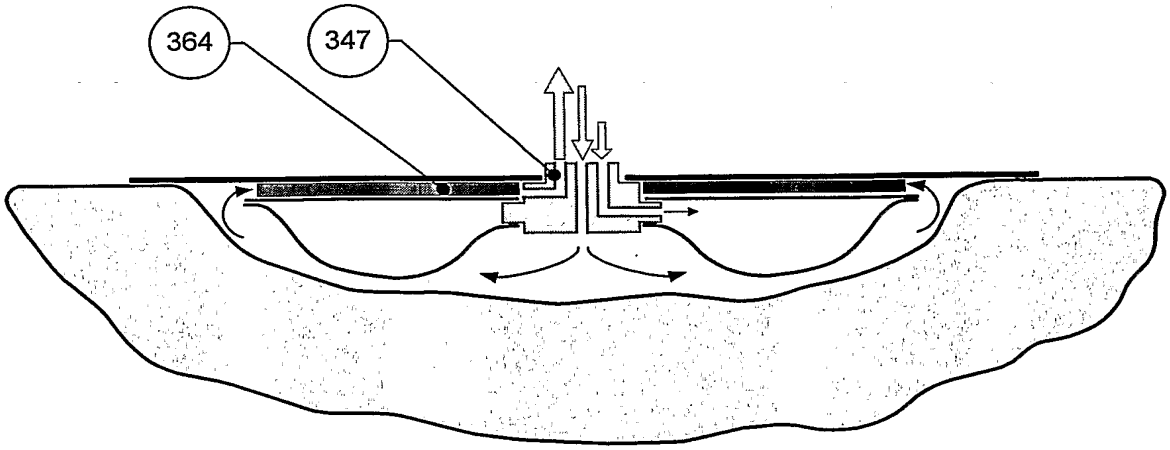

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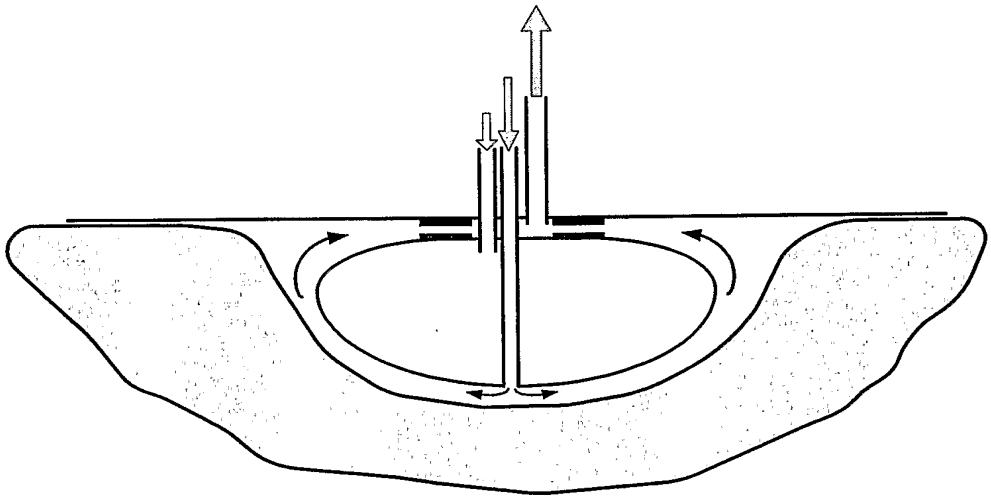

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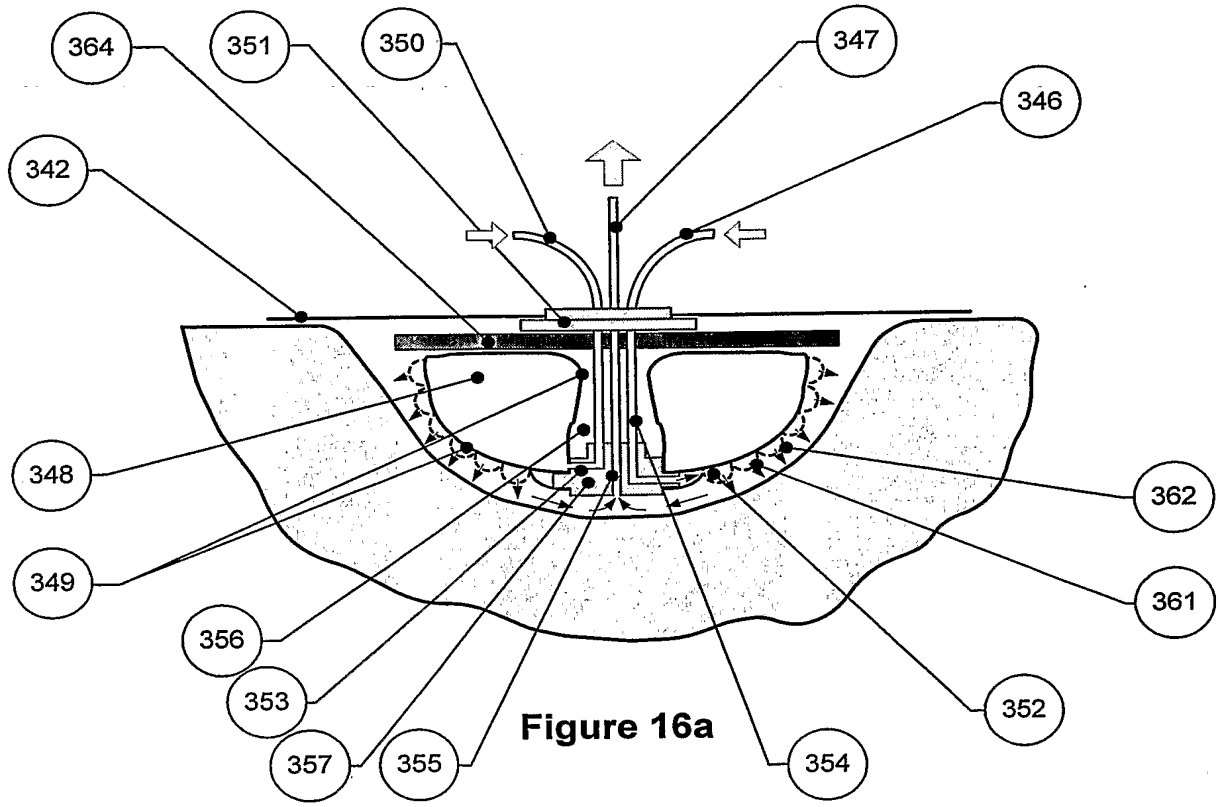

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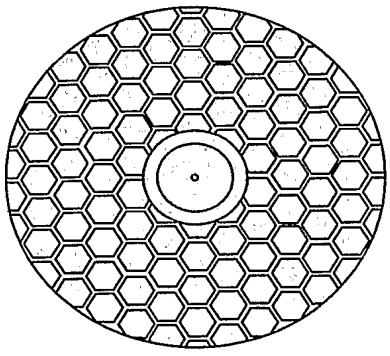

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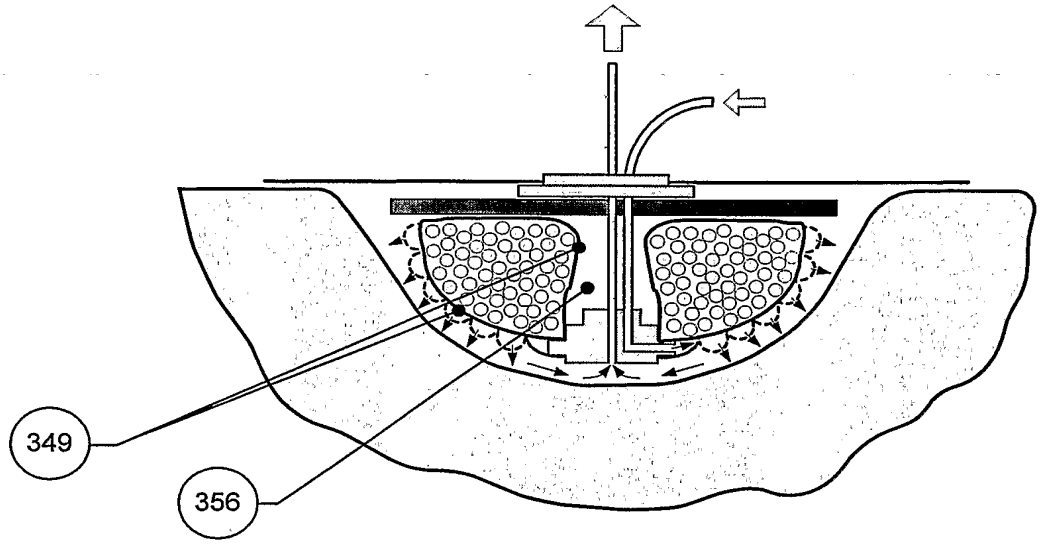

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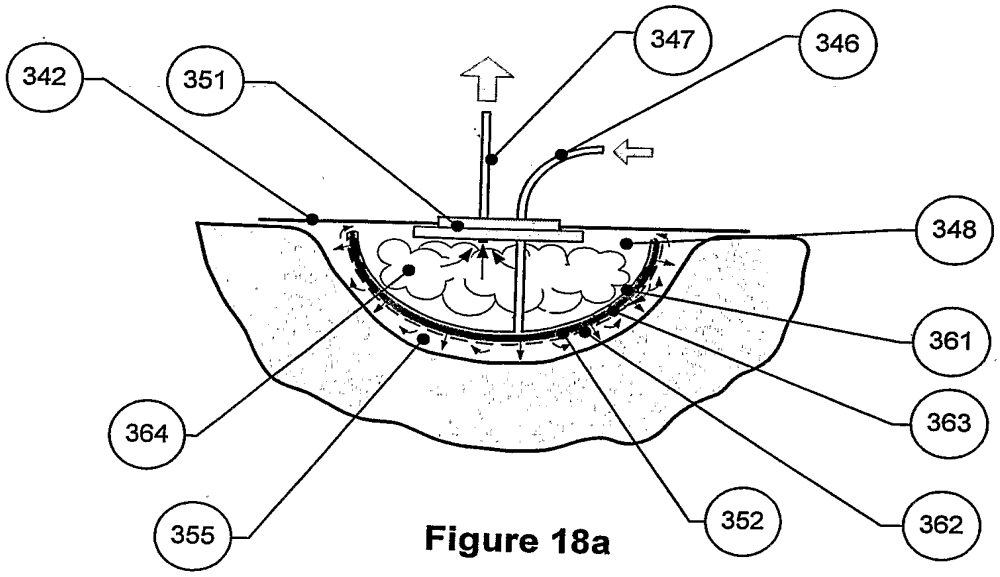

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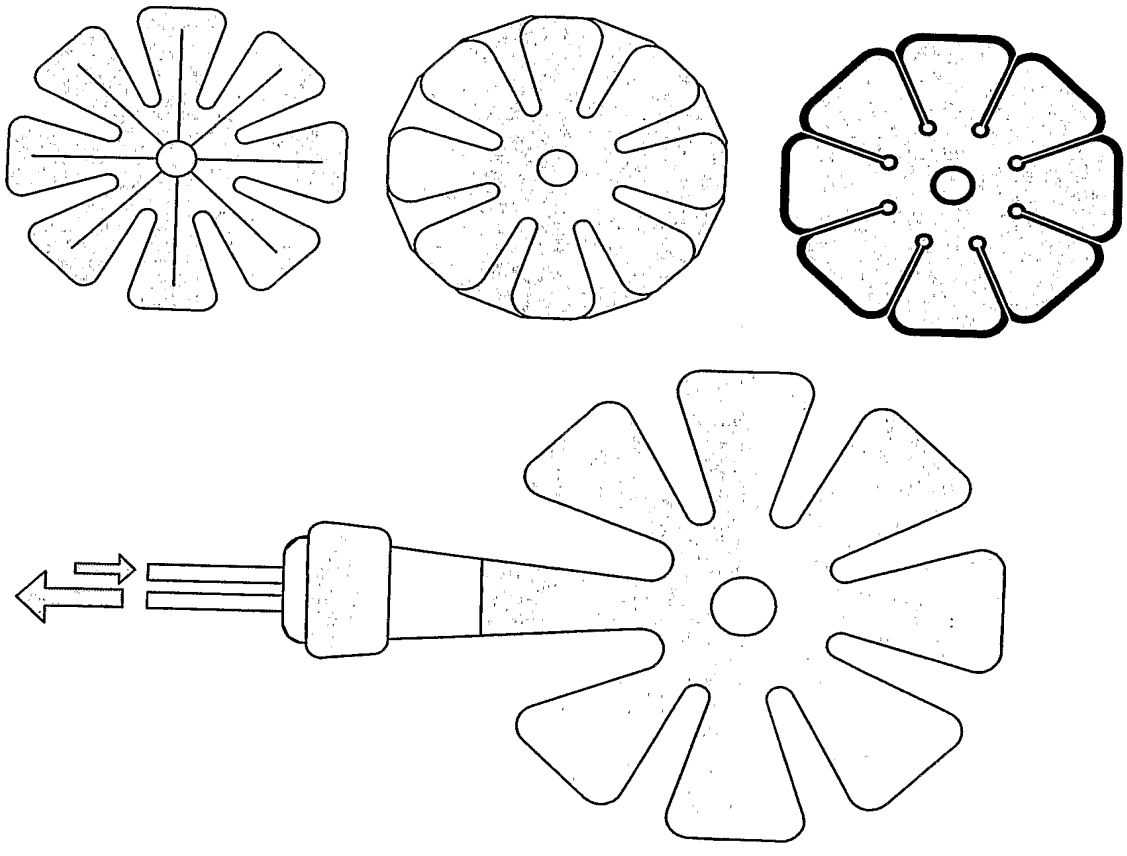

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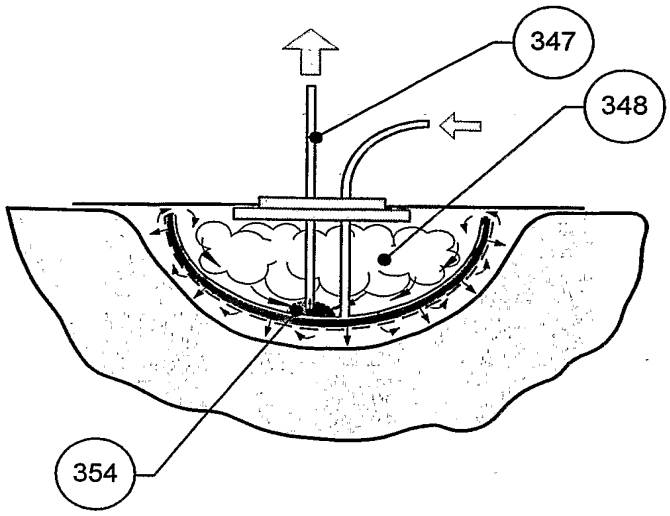

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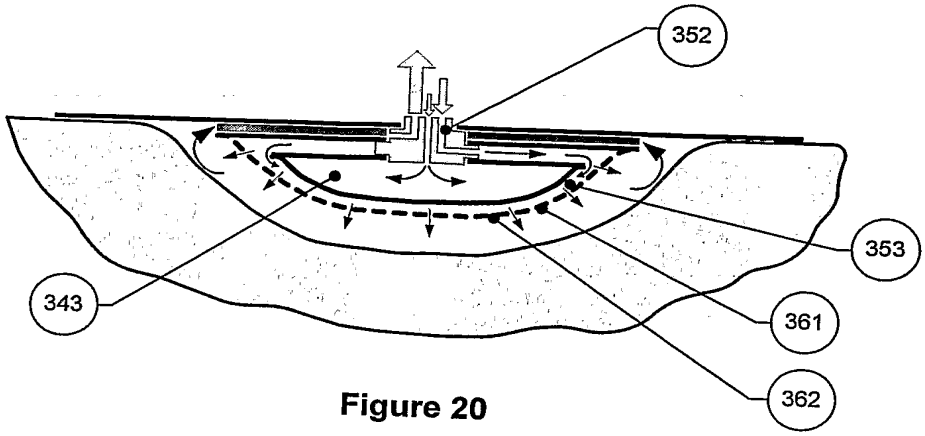

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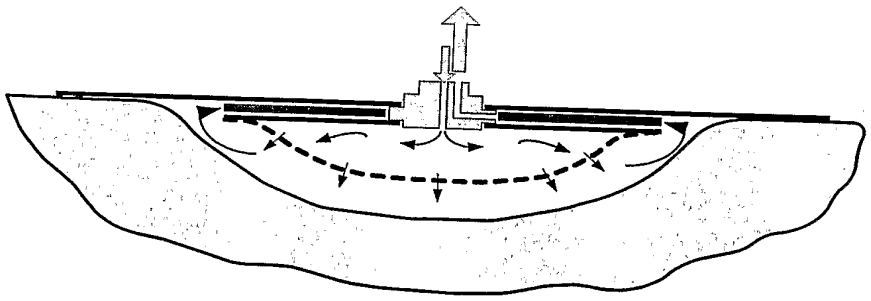

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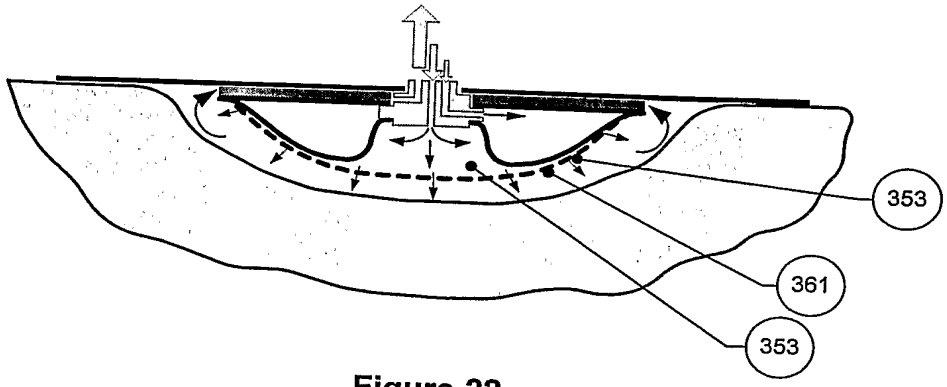
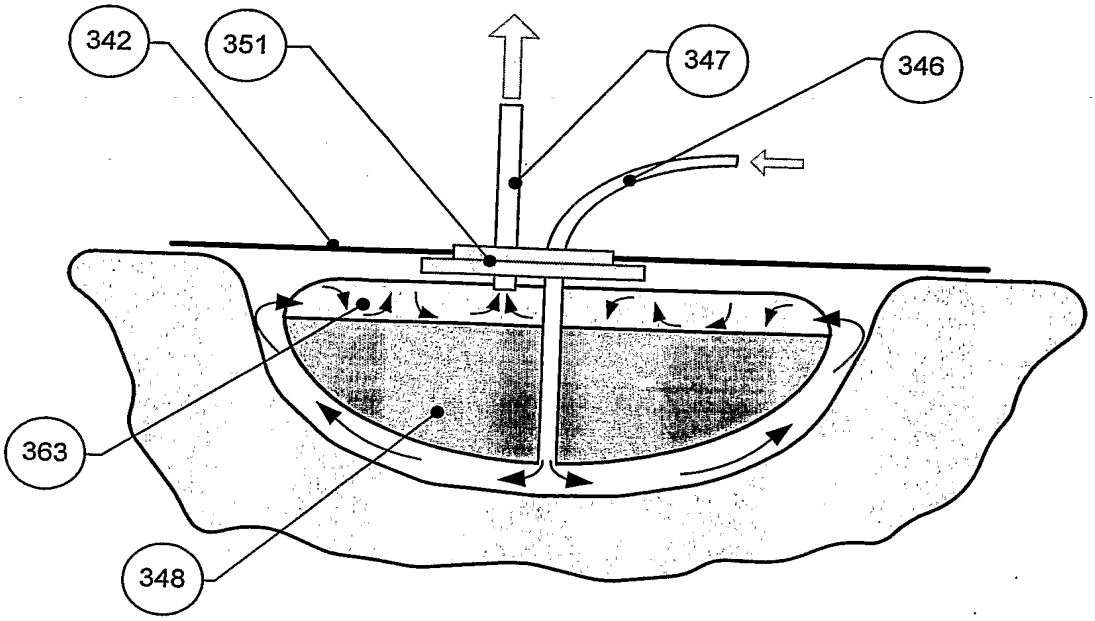


Figure 22



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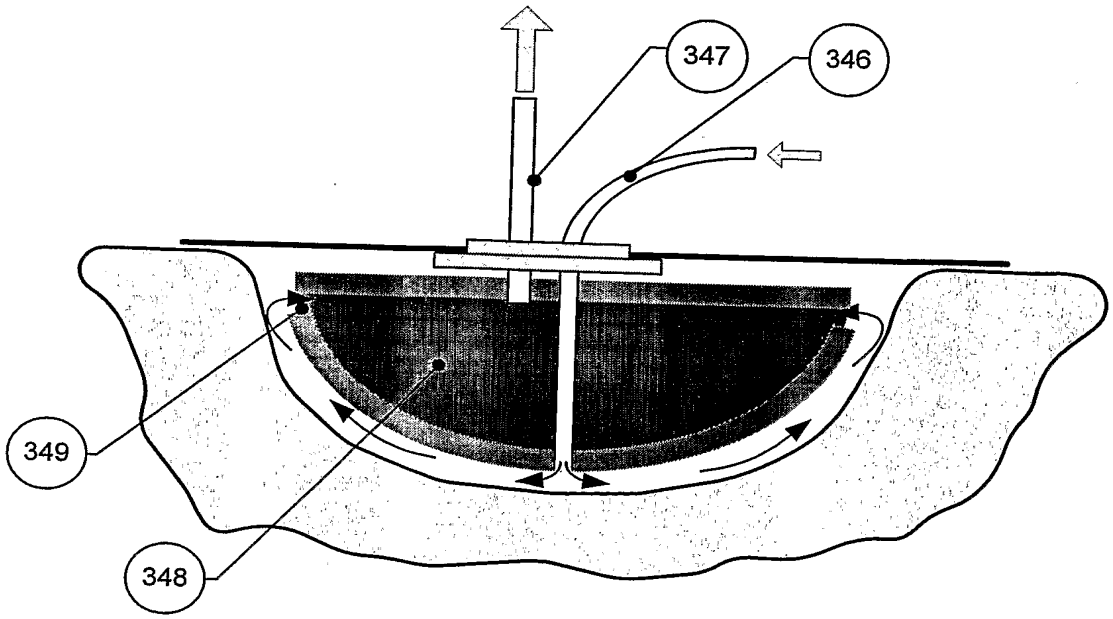

Figure 24

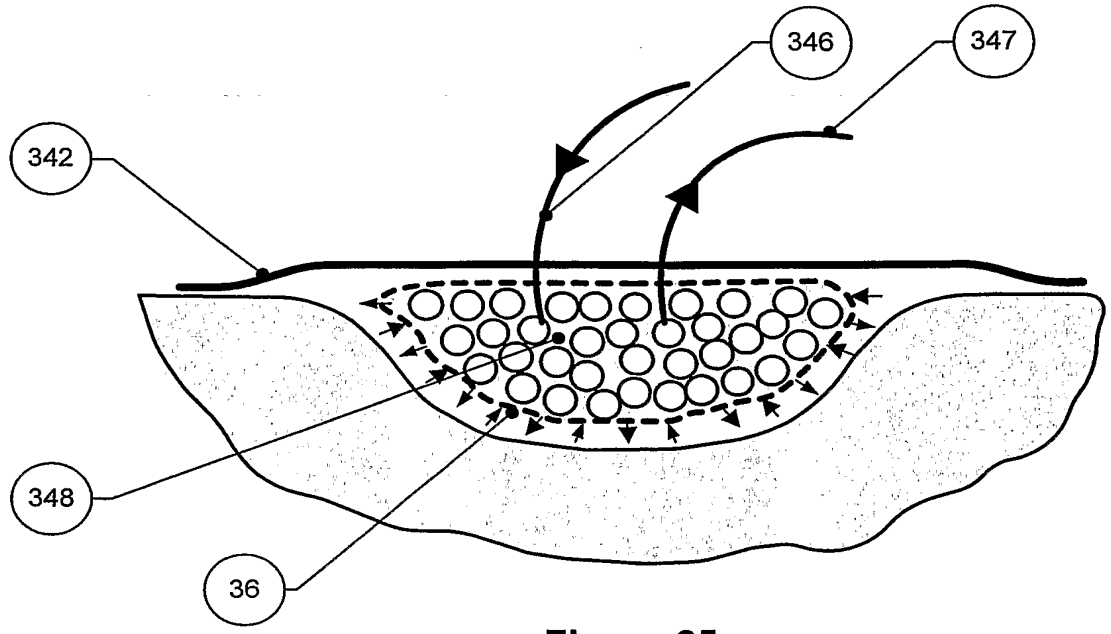

Figure 25

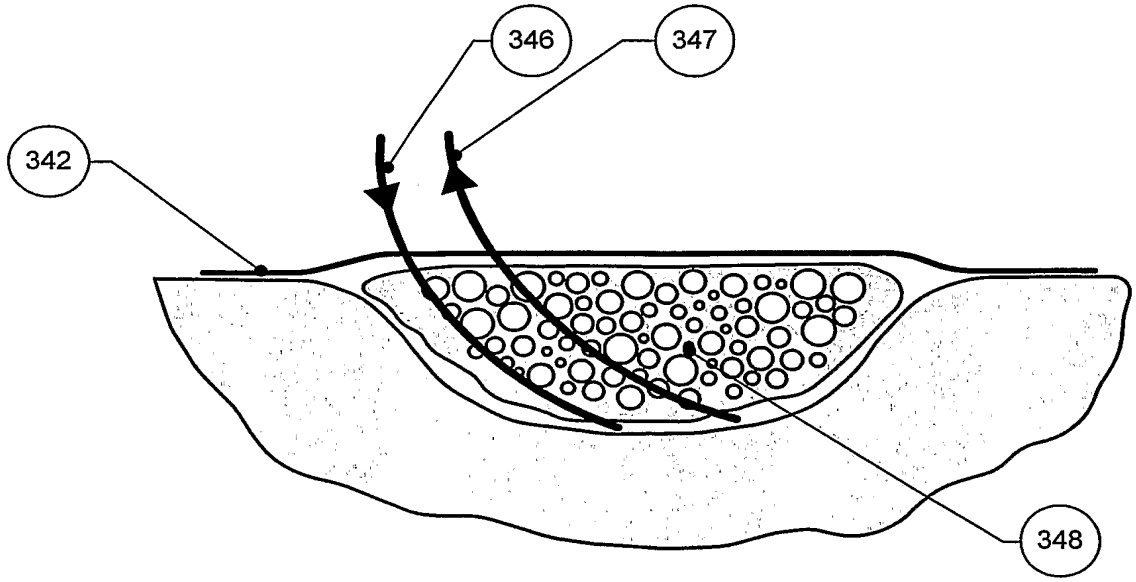

Figure 26